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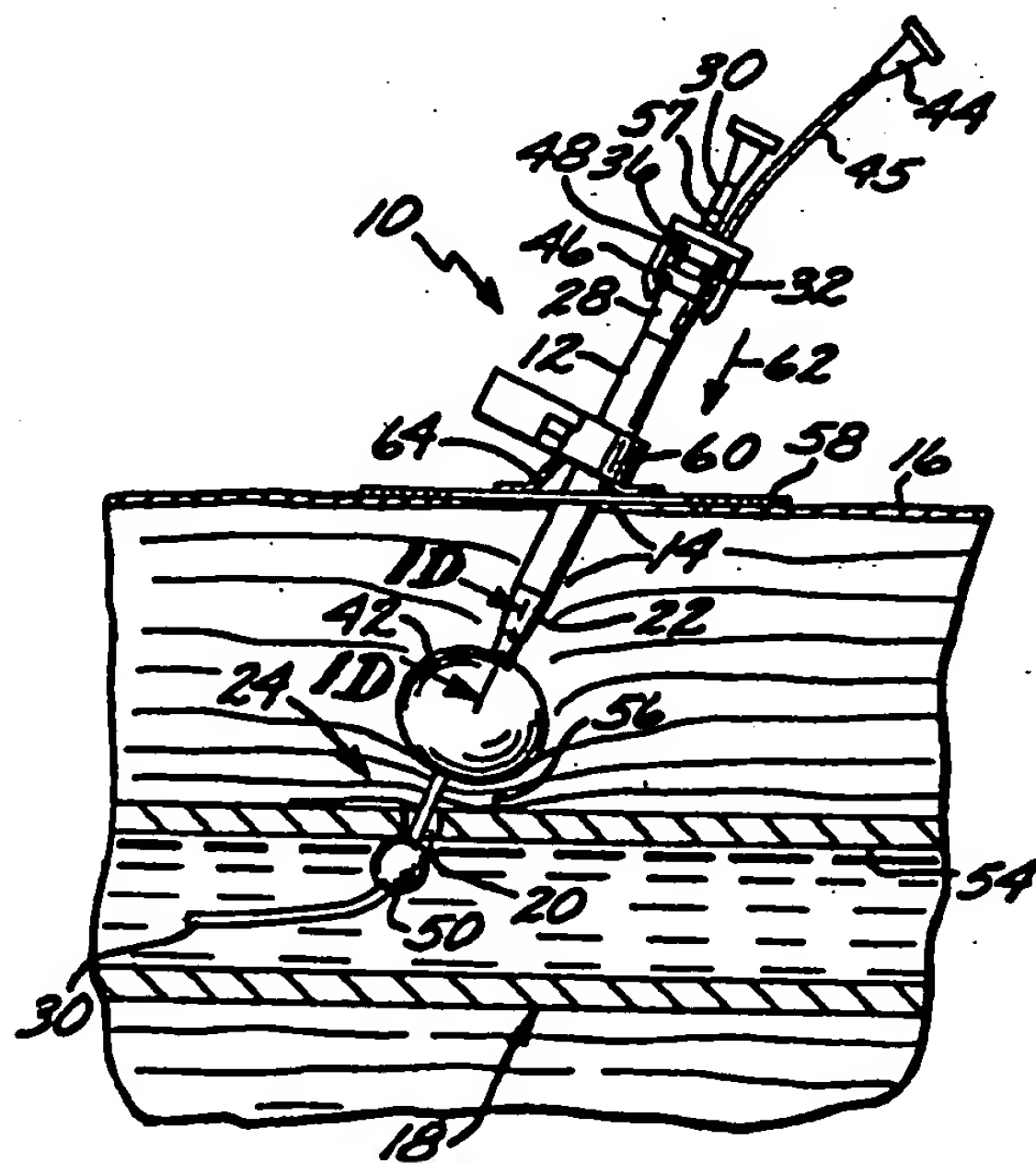
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(54) Title: APPARATUS AND METHOD FOR PERCUTANEOUS SEALING OF BLOOD VESSEL PUNCTURES

(57) Abstract

A device for promoting hemostasis in a blood vessel puncture is employed with an introducer that accesses the puncture through an incision. The introducer has an open distal end positionable at the puncture, an external portion with an open proximal end, and an axial channel therebetween. The device includes a hollow catheter, dimensioned to pass through the introducer channel, having a distal end to which is attached an expansible compression element, which may be an inflatable balloon, a collapsible prong assembly, or a resilient foam pad. Pressure is applied to the compression element through the introducer to promote hemostasis by the compression of subcutaneous tissue adjacent the puncture. The device preferably includes a locator member passing through the catheter and into the blood vessel through the puncture. The locator member may be either a guide wire, or a hollow tube with a locating balloon, disposed near the portion of the tube insertable into the vessel.



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1 APPARATUS AND METHOD FOR PERCUTANEOUS  
2 SEALING OF BLOOD VESSEL PUNCTURES

3 Background of the Invention

4 The present invention relates generally to the field of apparatus  
5 and methods for sealing wounds in the blood vessels of humans or  
6 animals. More specifically, the invention relates to a guided vascular  
7 compression device for percutaneously sealing arterial or venous  
8 punctures subsequent to surgical procedures, by promoting in situ  
9 hemostasis.

10 A large number of medical therapeutic and diagnostic procedures  
11 involve the percutaneous introduction of instrumentation into a vein or  
12 artery. For example, percutaneous transluminal coronary angioplasty  
13 (PTCA), most often involving access to the femoral artery, is performed  
14 hundreds of thousands of times annually, and the number of other such  
15 vessel-piercing procedures performed, e.g., percutaneous coronary  
16 angiography and atherectomy, has exceeded two million per year.

17 In each event, the closing and subsequent healing of the resultant  
18 vascular puncture is critical to the successful completion of the  
19 procedure. Traditionally, the application of external pressure to the  
20 skin entry site by a nurse or physician has been employed to stem  
21 bleeding from the wound until clotting and tissue rebuilding have sealed  
22 the perforation. In some situations, this pressure must be maintained  
23 for half an hour to an hour or more, during which the patient is  
24 uncomfortably immobilized, often with sandbags and the like. With  
25 externally applied manual pressure, both patient comfort and  
26 practitioner efficiency are impaired. Additionally, a risk of hematoma  
27 exists since bleeding from the vessel may continue until sufficient  
28 clotting effects hemostasis. Also, external pressure devices, such as

1 femoral compression systems, may be unsuitable for patients with  
2 substantial amounts of subcutaneous adipose tissue, since the skin  
3 surface may be a considerable distance from the vascular puncture site,  
4 thereby rendering skin compression inaccurate and  
5 thus less effective.

6 More recently, devices have been proposed to promote  
7 hemostasis directly at the site of the vascular perforation. One class of  
8 such puncture sealing devices features intraluminal plugs, as disclosed  
9 in U.S. Patents Nos. 4,852,568 - Kensey; 4,890,612 - Kensey; 5,021,059 -  
10 Kensey et al.; and 5,061,774 - Kensey. This class of device is  
11 characterized by the placement of an object within the bloodstream of  
12 the vessel to close the puncture.

13 Another approach to subcutaneous puncture closure involves  
14 delivery of tissue adhesives to the perforation site, as disclosed in U.S.  
15 Patent No. 5,383,899 - Hammerslag. Some likelihood exists of  
16 introducing the adhesive so employed disadvantageously into the  
17 bloodstream. U.S. Patent No. 4,929,246 - Sinofsky discloses the concept  
18 of applying pressure directly to an artery, and relies on the directing of  
19 laser energy through an optical fiber to cauterize the wound.

20 Yet another proposed solution to obviate the reliance on skin  
21 surface pressure is disclosed in U.S. Patent No. 5,275,616 - Fowler,  
22 wherein a cylindrical plug is inserted along the shaft of a catheter  
23 segment extending from the skin surface to the blood vessel. The  
24 catheter is then removed so that the plug can expand as fluid is drawn  
25 into the plug from the vessel and surrounding tissue. Unless pressure is  
26 applied, however, bleeding may occur around the plug into the  
27 subcutaneous tissue. Another approach that similarly deposits a plug

1 into the tissue channel is disclosed in U.S. Patent No. 5,391,183 -  
2 Janzen et al., which discloses a variety of plug delivery devices including  
3 threaded plug pushers and multilegged channels. As in the other  
4 disclosed methods for introducing a foreign plug into the incision, the  
5 Janzen et al. plug material, generally resorbable, is not removed from  
6 the patient once installed. Such permanent placement of foreign  
7 material into the body may result in inflammation or scar formation in  
8 the long term.

9 Furthermore, many of the prior art devices rely on tactile  
10 sensation alone to indicate to the surgeon the proper placement of the  
11 puncture closing instrumentation, and may require upstream clamping  
12 of the blood vessel to reduce intraluminal pressure to atmospheric at  
13 the puncture site.

14 As the foregoing description of the prior art demonstrates, none  
15 of the heretofore proposed solutions fulfills the need for a relatively  
16 simple, non-cautery apparatus and method for subcutaneously applying  
17 pressure directly to the vicinity of the vessel puncture by means of a  
18 pressure element that is removed from the patient once sealing of the  
19 puncture is achieved. There is a further need for a puncture sealing  
20 system that features use of instruments already in place at the access  
21 site so that the position for possible reentry is not lost, and the time  
22 required for the physician to change instrumentation is minimized.  
23 There is a still further need for a system that maintains pressure on the  
24 puncture site by lightweight mechanical means, thereby relieving the  
25 patient from the discomfort of external compression means, and freeing  
26 hospital personnel from constant surveillance of cumbersome external  
27 pressure structures for the duration of the hemostasis. There is also a

1 need for a hemostatic device that can be effectively employed  
2 regardless of the thickness of the tissue between the skin and the  
3 puncture site, by applying localized pressure close to the puncture site,  
4 rather than remote, diffused pressure to the skin surface.

5 Summary of the Invention

6 It is an object of this invention to provide a method and  
7 apparatus for sealing post-surgical vascular punctures that overcome the  
8 foregoing deficiencies.

9 It is a further object to apply pressure directly to the vicinity of  
10 the vascular puncture access site utilizing a subcutaneous pressure  
11 element that is removed permanently from the patient once hemostasis  
12 is achieved.

13 It is another object to employ an introducer instrument already  
14 in place at the access site to minimize instrumentation changing time,  
15 and to maintain access during an initial clotting period to facilitate  
16 possible reentry.

17 It is yet another object to maintain adequate hemostatic pressure  
18 on an adipose or fatty tissue layer above the puncture site in order to  
19 close the puncture naturally, to reduce the potential for  
20 pseudo-aneurysm formation, and to maintain such pressure by  
21 lightweight, non-labor intensive, mechanical means, thereby reducing  
22 patient discomfort.

23 The present invention involves a method for sealing a puncture  
24 site in a blood vessel, and apparatus for performing that method,  
25 wherein use is made of an introducer sheath (commonly referred to in  
26 the medical community as an "introducer") which is usually already in  
27 place inside the puncture site when a medical practitioner has

1 completed a procedure that requires intravascular access. Locator  
2 means, preferably either a locator tube (having an inflatable locating  
3 balloon), or a standard guidewire, is passed through the introducer and  
4 into the lumen of the vessel.

5 A semi-rigid catheter, including an expandable compression  
6 element at its distal end, and either two axial lumens (used in a  
7 compression balloon embodiment) or a single axial lumen (used in  
8 other embodiments), is inserted along the locator means fully into the  
9 introducer so that the expandable compression element at the distal  
10 end of the catheter is contained in an unexpanded state within the  
11 distal end of the introducer when the introducer is in a first or distal  
12 position relative to the catheter.

13 The introducer and the catheter are partially withdrawn together  
14 (moved proximally) from the puncture site until a preferred location  
15 above the vessel is achieved, the relative axial positions of the  
16 introducer and the catheter remaining unchanged, so that the  
17 introducer remains in its first or distal position relative to the catheter.  
18 This location is chosen to provide for a layer of fatty tissue above the  
19 puncture site between the compression element and the vessel. The  
20 extent of partial withdrawal is determined by the tactile sense of the  
21 practitioner, aided by a marker on a locator tube for the embodiment  
22 employing a locating balloon as the locator means, or by fluoroscopic  
23 viewing of a contrast medium, for the embodiment employing a  
24 guidewire as the locating means.

25 When the location is achieved, the introducer is moved to a  
26 second or proximal position relative to the catheter until the  
27 expandable compression element is revealed and expanded to bear on



1 the fatty tissue layer.

2 In another embodiment, the expandable compression element  
3 comprises an expandable prong assembly including a resilient spanning  
4 sheet for compressing the fatty tissue layer. In still another  
5 embodiment, the expandable compression element comprises a foam  
6 pad element bearing directly on the fatty tissue layer upon expansion  
7 when deployed from the introducer.

8 Once the compression element (balloon, prongs or foam tip) is in  
9 place, a lightweight holding arrangement is employed to maintain  
10 hemostatic pressure. The holding arrangement comprises an adhesive  
11 skin patch and fastener strips or bands bringing downward pressure on  
12 a sheath cuff clamped to the introducer. After an initial period of  
13 hemostasis, (approximately one to five minutes), the locator means  
14 (locator balloon tube or guidewire) is removed from the puncture and  
15 the apparatus. After another five to twenty-five minutes of pressure on  
16 the puncture, the expandable distal end element (compression balloon,  
17 prongs or foam) is collapsed, and the introducer and catheter are  
18 permanently removed from the patient.

19 These and other features and advantages of the present invention  
20 will be more readily apparent from the Detailed Description that  
21 follows.

## 22 Brief Description of the Drawings

23 Fig. 1 is an elevational view, partially in cross section, illustrating  
24 a first preferred embodiment of the present invention;

25 Fig. 1A is an elevational view, partially in cross section,  
26 illustrating the initial position in a puncture site of the distal portion of  
27 the apparatus of Fig. 1;



1        Fig. 1B is an elevational view, partially in cross section,  
2        illustrating the apparatus of Fig. 1A in a preferred operational position;

3        Fig. 1C is an elevational view, partially in cross section,  
4        illustrating the apparatus of Fig. 1A with the compression balloon  
5        revealed and not yet inflated;

6        Fig. 1D is a cross sectional view taken along lines 1D-1D of Fig.  
7        1, illustrating the dual lumen configuration of a catheter element of the  
8        apparatus of Fig. 1;

9        Fig. 2 is an elevational view, partially in cross section, of a second  
10       preferred embodiment of the present invention, showing the  
11       compression mechanism of this embodiment in a retracted state near a  
12       vascular puncture site;

13       Fig. 2A is a perspective view of the embodiment of Fig. 2,  
14       showing the compression mechanism in an expanded state;

15       Fig. 2B is a view similar to that of Figure 2, showing the  
16       compression mechanism deployed, in its expanded state, at a vascular  
17       puncture site;

18       Fig. 3 is an elevational view, partially in cross section, of a third  
19       preferred embodiment of the present invention, showing the  
20       compression mechanism of this embodiment in a retracted state near a  
21       vascular puncture site;

22       Fig. 3A is a view, similar to that of Fig. 3, illustrating the  
23       compression mechanism in an expanded state;

24       Fig. 4 is a perspective view of a fourth preferred embodiment of  
25       the present invention;

26       Fig. 4A is an elevational view, partially in cross section,  
27       illustrating the initial position in a puncture site of the introducer and

1 guidewire elements of the apparatus of Fig. 4;

2 Fig. 4B is a view similar to that of Fig. 4A, but showing a a  
3 catheter contained within introducer when the introducer is in a first  
4 axial position relative to the catheter;

5 Fig. 4C is an elevational view, partially in cross section,  
6 illustrating the apparatus of Fig. 4A in a preferred operational position;

7 Fig. 4D is an elevational view, partially in cross section,  
8 illustrating the apparatus of Fig. 4A with the compression balloon  
9 revealed and not yet inflated, the introducer having been moved to a  
10 second axial position relative to the catheter;

11 Fig. 4E is a perspective view, partially in cross section, illustrating  
12 the compression balloon of the apparatus of Fig. 4D in an inflated  
13 state;

14 Fig. 4F is an elevational view, partially in cross section,  
15 illustrating the apparatus of Fig. 4E with the guidewire element  
16 withdrawn; and

17 Fig. 5 is an elevational view, partially in cross section, illustrating  
18 a modification of the embodiment of Fig. 1.

19 Detailed Description of the Preferred Embodiments

20 1. Structure of the Apparatus

21 A percutaneous blood vessel sealing device, or percutaneous  
22 hemostatic device 10, which applies hemostatic sealing pressure directly  
23 to tissue adjacent a vascular puncture site, without employing implanted  
24 materials, is shown in Fig. 1.

25 In each exemplary embodiment described herein, an introducer  
26 sheath ("introducer") 12, well known in the art, is present in an incision  
27 14 that extends from the skin surface 16 to a blood vessel (artery or

1 vein) 18 of a patient at the site of a blood vessel puncture 20. The  
2 introducer 12 has normally been inserted previously to provide access to  
3 the vessel 18 for instrumentation (not shown) used in performing a  
4 vascular procedure immediately preceding the need to seal the puncture  
5 20. The initial position of an introducer 12 so inserted is most clearly  
6 illustrated in Fig. 4A, which shows a tapered distal end 22 of the  
7 introducer 12 at a puncture site 24, inserted within a vascular puncture  
8 20. Typically, the introducer 12 will have a size of approximately 7  
9 French (2.3 mm in diameter), and a length of approximately 130 mm,  
10 although a size as large as 14 French (4.7 mm in diameter) may be used  
11 for larger punctures.

12 A working channel 26, best seen in Fig. 1D, extends axially from  
13 the proximal end 28 of the introducer 12 through its tapered distal end  
14 22. In the first preferred embodiment of Figures 1 through 1D, a  
15 hollow locator tube 30 extends coaxially through the introducer 12 and  
16 into the vessel 18 through the puncture 20. Guided by the locator tube  
17 30 into the introducer working channel 26 is a semi-rigid catheter 32  
18 having a catheter proximal end 33, and a catheter distal end 34 (Fig.  
19 1A). The introducer 12 is movable axially with respect to the catheter  
20 32, and is disposed initially at a first axial position, or distal position, in  
21 which the catheter distal end 34 is enclosed or sheathed within the  
22 distal end 22 of the introducer 12.

23 The catheter 32 is a dual-lumen device having a first axial lumen  
24 36 (Fig. 1D) which encompasses the locator tube 30 when the catheter  
25 32 is inserted into the working channel 26 of the introducer 12. A  
26 second axial lumen 38 is provided with an inflation orifice 40 near its  
27 distal end, the inflation orifice communicating with the interior of a

1 compression balloon 42 that concentrically surrounds a portion of the  
2 length of the catheter 32 extending proximally from its distal end 34.  
3 The compression balloon 42 is initially enclosed, in an uninflated state,  
4 within the distal end 22 of the introducer 12, as illustrated in Fig. 1A.  
5 The opposite (proximal) end of the second axial lumen 38  
6 communicates with a compression balloon inflation port 44 through an  
7 inflation tube 45, as shown in Figures 1 and 4. Overall, the catheter 32  
8 has an outer diameter sufficiently small to be freely insertable into the  
9 introducer 12, and a length that is greater than that of the introducer  
10 12, i.e., in the range of about 130 mm to about 750 mm.

11 At the proximal end 28 of the introducer 12 is a well-known luer  
12 type lock fitting 46 configured to mate with a catheter proximal end  
13 luer fitting 48 when the introducer 12 and the catheter 32 are in a final  
14 operational position, as determined by manipulation of the locator tube  
15 30, as will be described below. The locator tube 30 has an inflatable  
16 intravascular locating balloon 50 at its distal end portion, shown in Fig.  
17 1A in an uninflated state. The interior of the locating balloon 50 is in  
18 fluid communication with the hollow interior of the locator tube 30  
19 through a suitable inflation orifice (not shown), as is well known in  
20 conventional balloon catheters and the like.

21 Although the luer locks 46, 48 may be employed for both the  
22 locator balloon embodiment (Figures 1 through 1D) and for  
23 embodiments (described below) featuring expandable compression  
24 elements other than the compression balloon 42, a version using no luer  
25 locks will be described below that is specifically adapted for use with  
26 the compression balloon 42. Both the luer and non-luer versions are  
27 suitable for embodiments employing either the inflatable locating

1 balloon 50 or a guidewire locating means, to be described below.

2       Returning now to Figures 1A through 1C, a progression of  
3 locating positions for the device 10 is illustrated. Figure 1A shows the  
4 locator tube 30, having the uninflated locating balloon 50 near its distal  
5 end, inserted into the vessel 18 through the introducer 12 and the  
6 vascular puncture 20. It is advantageous to construct the locator tube  
7 30 so that a length of tube extends distally beyond the location of the  
8 locating balloon 50 into the vessel 18 to facilitate re-access through the  
9 vascular puncture 20, if required. The entire apparatus 10 (including  
10 the introducer 12 and the catheter 32) is in its initial position relative to  
11 the vessel; that is, the distal tip 22 of the introducer 12 is located  
12 adjacent to or within the puncture 20, while the introducer 12 is in its  
13 above-described first axial position or distal position relative to the  
14 catheter 32, in which the catheter distal end 34 and the uninflated  
15 compression balloon 42 are enclosed within the distal end 22 of the  
16 introducer 12.

17       Figure 1B illustrates the device 10 after the locating balloon 50  
18 has been inflated by fluid introduced into it via the locator tube 30.  
19 The entire device 10 (including the introducer 12 and the catheter 32)  
20 has been partially withdrawn from the puncture site 24 in the direction  
21 of the arrow 52 (i.e., in the proximal direction), to a "preferred  
22 operational position", in which the locating balloon 50 is lodged against  
23 an interior wall 54 of the vessel 18. The introducer 12 remains in its  
24 first or distal position, in which the portion of the catheter 32 carrying  
25 the uninflated compression balloon 42 is enclosed within the distal end  
26 22 of the introducer 12.

27       In Figure 1C, the introducer 12 has been moved axially, relative

1 to the catheter 32, in the direction of the arrow 52 (i.e., proximally), to  
2 its second axial position, or proximal position. The movement of the  
3 introducer 12 to this second or proximal position uncovers the  
4 uninflated compression balloon 42.

5 The compression stage of the device 10 is illustrated next in Fig.  
6 1. The compression balloon 42, inflated via the second axial lumen 38  
7 (Fig. 1D), rests in an optimal position to effect natural hemostasis, viz.,  
8 above a laminar portion 56 of the fatty tissue adjacent the puncture site  
9 24. An optimal distance from the vessel 18 to the catheter distal end  
10 34 is in the range of 2 mm to 10 mm. This distance will dispose a layer  
11 of fatty tissue 56 between the vessel 18 and the catheter 32, minimizing  
12 the potential for pseudo-aneurysm. The introducer luer lock 46 is  
13 shown engaged with the catheter luer lock 48, assuring that a holding  
14 force applied to the introducer 12 will be transmitted as well to the  
15 catheter 32. In addition, a visible marker band 57 on the exterior of  
16 the locating tubing 30 may advantageously be provided to align the  
17 proximal ends of the introducer 12 and the catheter 32 in  
18 correspondence with the location of the distal ends 22, 34 thereof when  
19 the locator balloon 50 is lodged against the inner wall 54 of vessel 18.

20 An adhesive skin patch 58 with a sheath cuff 60 clamped onto  
21 the external portion of the introducer 12 to apply downward force (in  
22 the direction of the arrow 62, i.e., distally) on the introducer 12 is  
23 shown in Figures 1 and 4. Fastener strips 64 secure the adhesive patch  
24 58 to the sheath cuff 60. The fastener strips 64 may be elastic bands  
25 with suitable adhesive areas, or hook and loop strips (such as the type  
26 marketed under the trademark VELCRO) that adhere to areas of  
27 complementary material on the patch 58. Pressure maintained by the

1 introducer sheath cuff 60 on the catheter 32 provides hemostatic  
2 pressure on the compression balloon 42 to bear on the tissue layer 56  
3 for a first period of time, whereupon the locating tube 30 is withdrawn  
4 (the locator balloon 50 having first been deflated), and a second period  
5 of time elapses, after which all instrumentation is removed from the  
6 patient as will be noted when the method for sealing the puncture 20 is  
7 described in detail below.

8 Another embodiment of the present invention is illustrated in  
9 Figures 2, 2A, and 2B, which show a collapsible prong assembly  
10 compression element 66 attached to the catheter distal end 34. The  
11 prong assembly 66 is radially compressed or collapsed when enclosed  
12 within the introducer 12, when the introducer is in its first or distal  
13 position. The prong assembly 66 expands radially when the introducer  
14 12 is partially withdrawn from the vessel 18 (Figures 2A and 2B), by  
15 moving the introducer 12 to its second or proximal position in a  
16 manner similar to the partial withdrawal of introducer 12 in the  
17 direction of arrow 52 as described previously in connection with the  
18 compression balloon embodiment.

19 The prong assembly 66 comprises a plurality of spaced-apart  
20 resilient prongs 68, the proximal ends of which are attached to the  
21 catheter 32, and the distal ends of which are attached to a collapsible  
22 spanning film sheet or dam 70, shown expanded in Figures 2A and 2B.  
23 The sheet or dam 70 allows the application of hemostatic pressure on  
24 the tissue 56 above the vessel 18. A central aperture 72 in the sheet or  
25 dam 70 permits the locator tube (not shown) to project through the  
26 catheter 32 into the vessel 18 as described previously. Since there is no  
27 compression balloon to be inflated, a catheter with a single axial lumen



1 36 is adequate for this application. Materials for the spanning sheet or  
2 dam 70 may include polyurethane and polyethyleneterephthalate (PET).

3 Still another embodiment of the invention is illustrated in Figures  
4 3 and 3A, which show a foam pad compression element 74 attached to  
5 the catheter distal end 34. The foam pad element 74 is compressed  
6 when enclosed within the introducer 12 when the introducer is in its  
7 first or distal position. The foam pad compression element 74 then  
8 expands when the introducer 12 is partially withdrawn from the vessel  
9 18, as shown in Fig. 3A, by moving the introducer 12 to its second or  
10 proximal position, as described above with respect to the first and  
11 second embodiments. Hemostatic pressure is similarly exerted on the  
12 tissue 56 above the vessel 18. An axial channel 76 in the foam pad 74  
13 permits the locator tube (not shown) to project through the catheter 32  
14 into the vessel 18, as described previously. As with the expanding  
15 prong embodiment above, since there is no compression balloon to be  
16 inflated, a catheter with a single axial lumen 36 is adequate for this  
17 embodiment. Materials for the foam pad 74 may include various  
18 polymeric foams, such as polyurethanes, as are well-known in the art.  
19 The foam pad 74 may be impregnated with a coagulant such as  
20 thrombin or protamine to effect local hemostasis.

21 The foregoing embodiments, featuring both the luer locking of  
22 the introducer 12 with the catheter 32, and a variety of expandable  
23 compression elements 42, 66, 74 at the catheter distal end 34, employ a  
24 locator tube 30 with a locating balloon 50 to determine the optimal  
25 operational location for the apparatus 10. In lieu of a locating balloon  
26 50, a guidewire 78 may be utilized for the location determination of the  
27 apparatus 10, as illustrated in Figures 4 through 4F.

1 In Fig. 4A, a standard guidewire 78, typically 3 French (1 mm in  
2 diameter), shown coaxially located within the introducer 12, has a distal  
3 end 82 extending out of the introducer distal end 22 into the puncture  
4 20 of the vessel 18.

5 The catheter 32 is shown in Fig. 4B having been inserted into the  
6 introducer 12 and guided to the distal end 22 of the introducer by the  
7 guidewire 78. At the distal end 34 of the catheter 32 is a radiopaque  
8 marker 84 for viewing under fluoroscopy, as shown in Fig. 4D.

9 Figure 4C shows an optimal location for catheter distal end 34,  
10 radiopaque contrast medium (not shown) having been introduced into  
11 the catheter lumen 36, and the apparatus 10 having been partially  
12 withdrawn from the vessel 18 in the direction of the arrow 52 (i.e.,  
13 proximally). An extravasation 85 of the radiopaque contrast medium is  
14 shown marking the desired distance between the vessel 18 and the  
15 catheter distal end 34, as will be explained when the method for sealing  
16 the puncture is described below.

17 The introducer 12 is shown in Fig. 4D having been moved, in the  
18 direction of the arrow 52, to its second or proximal position to reveal  
19 the uninflated compression balloon 42 in position for inflating. Figure  
20 4E illustrates the apparatus 10 with the compression balloon 42 inflated  
21 and in place above the fatty layer 56 to apply hemostatic pressure for a  
22 first period of time in order to effect initial closure of puncture site 24.  
23 Figure 4F shows the apparatus 10 after the guidewire 78 has been  
24 removed from the apparatus 10 and pressure is applied for a second  
25 period of time to close the puncture 20.

26 In analogous fashion, the guidewire 78 and radiopaque  
27 positioning of an expandable compression element at the distal end 34

1 of the catheter 32 may be employed with the prong assembly and foam  
2 pad embodiments described above in connection with the locator tube  
3 30. For introducing the radiopaque or contrast medium (not shown)  
4 into the catheter lumen 36, a standard hemostatic "Y" 86 is used, as  
5 shown in Fig. 4. The "Y" 86 has a main leg 88 for receiving the  
6 guidewire 78 into the axial lumen 36 of the catheter 32, while a side  
7 port 90 of the "Y" 86 is used for introducing the contrast medium into  
8 the same lumen.

9 A modification of the first (compression balloon)  
10 embodiment of the present invention is shown in Fig. 5, where an  
11 apparatus 110 has an introducer 112 having no luer connection with a  
12 catheter 132. Since the cuff 60 applies downward force in the direction  
13 of the arrow 62 only to the introducer 112, and not to the catheter 132,  
14 the distal end 122 of the introducer 112 must bear directly on the  
15 compression balloon 42 to exert hemostatic pressure on the balloon 42.  
16 Although this modification is suitable only for the compression balloon  
17 embodiment of this invention, both the locator tube 30 and the  
18 guidewire 78 may be utilized in this modification for optimal positioning  
19 of the catheter distal end 34.

## 20 2. Method for Sealing Vascular Punctures

21 A brief review of a typical vascular entry procedure may be of  
22 value in describing the puncture closure technique of the present  
23 invention. To initiate one of the common operations such as the PTCA  
24 (Percutaneous Transluminal Coronary Angioplasty) mentioned above, a  
25 piercing cannula is inserted into the skin of a patient at an angle of  
26 from 25 to 45 degrees until it punctures a blood vessel, e.g., the femoral  
27 artery. The vessel may be located one centimeter or more beneath the

1 surface of the skin. A guidewire is inserted through the cannula into  
2 the vessel, the cannula is withdrawn, and a catheter introducer sheath is  
3 inserted over the guidewire into the puncture site.

4 The practitioner then uses the introducer to gain access to the  
5 vascular lumen for the instrumentation used to perform the particular  
6 procedure. At the conclusion of the procedure, the introducer is the  
7 last device remaining in the puncture, which must then be sealed.

8 The method of the present invention provides a rapid,  
9 permanent, inexpensive sealing of a puncture in a blood vessel, with no  
10 foreign implants remaining in the patient. The method can be  
11 understood with reference to the drawing figures and the previous  
12 description of the apparatus of this invention.

13 In Fig. 1A, an introducer sheath 12 is shown in a puncture site 24  
14 at the conclusion of a vascular procedure. According to one  
15 embodiment of the present invention, a locator tube 30 having an  
16 inflatable locating balloon 50 adjacent its distal end is inserted axially  
17 through the introducer 12, into a puncture 20 and extending the  
18 uninflated locating balloon 50 into the lumen of a vessel 18.

19 A dual lumen catheter 32 is passed over the locator tube 30 so  
20 that a first lumen 36 (Fig. 1D) of the catheter 32 receives the locator  
21 tube 30. The locator tube 30 maintains alignment of the catheter 32  
22 with the puncture 20 and allows repeated access into the vessel 18, if  
23 necessary. The catheter 32, having an inflatable compression balloon  
24 42 at its distal end 34, is inserted fully into the introducer 12 until its  
25 distal end 34, including the uninflated compression balloon 42, is at the  
26 distal end 22 of the introducer 12. At this stage, the locator tube 30 is  
27 pushed or pulled until a marker band 57 (shown in Fig. 1) is aligned

1 with the proximal end 33 of the catheter 32. The marker band 57 is  
2 preselected to establish a fixed relationship with the catheter 32 so that  
3 a preferred distance may be maintained between the vessel 18 and the  
4 distal end 34 of catheter 32 as will be explained below. The introducer  
5 12 being in its first or distal position, the uninflated compression  
6 balloon 42 is fully enclosed and contained within the working channel  
7 26 of the introducer 12, as described above.

8 The practitioner then inflates the locating balloon 50 via the  
9 locator tube 30, partially withdrawing the introducer 12, the catheter 32  
10 and the locator tube 30 from the puncture 20 in the direction of the  
11 arrow 52, until the locating balloon 50 lodges against the inner wall of  
12 the vessel 18 at the puncture 20, as illustrated in Fig. 1B. Since the  
13 position of the catheter distal end 34 relative to the introducer distal  
14 end 22 remains unchanged, the distal end 34 of the catheter is now at  
15 the location predetermined by the placement of the marker band 57,  
16 preferably about 5 mm to 15 mm from the puncture 20. This distance  
17 will allow a layer of fatty subcutaneous tissue 56 to lie between the  
18 catheter distal end 34 and the puncture 20.

19 Once the catheter distal end 34 is in the desired location, the  
20 introducer 12 is further withdrawn in the direction of the arrow 52, by  
21 moving it to its second or proximal position relative to the catheter 32,  
22 as described above, to expose the uninflated compression balloon 42, as  
23 shown in Fig. 1C. The luer fittings 46, 48 at the proximal ends of the  
24 catheter 32 and the introducer 12, respectively, are now connected to  
25 each other to lock the catheter 32 and the introducer 12 into a fixed  
26 position relative to one another, and the compression balloon 42 is then  
27 inflated, as illustrated in Fig. 1, via a second catheter lumen 38 (Fig.

1D). The compression balloon 42 is then pressed down against the fatty layer 56 above the puncture site 24, while gentle traction is maintained on the locating balloon 50, thus compressing the extravascular fatty tissue 56 between the balloons 42, 50. The fatty tissue 56 advantageously minimizes the potential of pseudo-aneurysm formation and promotes efficient hemostasis.

To assist in maintaining pressure on the vessel 18, an introducer cuff 60 is clamped onto the introducer 12 and secured to an adhesive patch 58 by means of elastic or hook and loop fastening strips 64 (Figs. 1 and 4). When the introducer 12 is locked with the catheter 32 by the luer fittings 46, 48, the downward force provided by the fastening strips 64 is transmitted from the introducer 12 through the semi-rigid catheter 32 to the compression balloon 42, maintaining hemostatic pressure on the puncture site 24 through fatty tissue 56.

After a first period of time (approximately 5 to 15 minutes), initial clotting of the puncture 20 will have occurred. The locating balloon 50 is then deflated and the locator tube 30 withdrawn from the apparatus 10, leaving only a small (e.g., approximately 1 mm in diameter) portion of the original puncture 20 to clot. The compression balloon 42 remains in place for an additional (second) period of time (approximately 5 to 25 minutes), providing hemostasis to the puncture 20, after which the compression balloon 42 is deflated and retracted proximally into the introducer 12, the luer fittings 46, 48 having first been disconnected. The sealing process having been completed, the apparatus 10 is completely removed from the patient.

The foregoing method uses an introducer 12 that is already positioned at the access site so that position is not lost in changing



1 instruments, bleeding does not occur while devices are positioned, and  
2 the locator tube 30 maintains the access location for re-access if needed  
3 during the initial clotting of the puncture 20. Furthermore,  
4 employment of the present invention requires minimal physician time  
5 and greatly reduces staff time and involvement previously devoted to  
6 maintaining supradermal pressure for long periods of hemostasis. In  
7 addition, the need for operating room time may be reduced by the  
8 removal of the locator tube 30, the introducer 12 and the catheter 32  
9 after the patient is returned to the patient's room. Overall, patient  
10 discomfort is significantly lessened through the use of the foregoing  
11 method as compared with the traditional manual external compression  
12 techniques.

13         Similar steps are followed for implementing the method of the  
14 present invention with the second embodiment of the apparatus  
15 described above. In the second embodiment, the compression element  
16 at catheter distal end 34 comprises the collapsible prong assembly 66, as  
17 shown in Figures 2, 2A, and 2B. In this second embodiment, once the  
18 introducer distal end 22 is in its initial (first or distal) position (about 5  
19 to 15 mm from the vessel 18) as shown in Fig. 2, the movement of the  
20 introducer 12 to its second or proximal position releases the prong  
21 assembly 66 from confinement within the introducer 12, allowing the  
22 individual prongs 68 of the prong assembly 66 to expand, as illustrated  
23 in Fig. 2A. A resilient spanning sheet or dam 70, supported by the  
24 ends of the prongs 68, then allows the application of hemostatic  
25 pressure on the fatty tissue layer 56, as described earlier in connection  
26 with the compression balloon embodiment. The locator tube (not  
27 shown) passes through and is withdrawn from the aperture 72 in the



1 spanning film 70.

2 A third embodiment of the method, following steps substantially  
3 identical to the above described procedures, involves the use of the  
4 compressible foam pad 74 shown in Figs. 3 and 3A as the compression  
5 element at the distal end 34 of the catheter 32.

6 In this third embodiment, when the catheter 32 is in the  
7 preferred location as shown in Fig. 3, the introducer 12 is moved from  
8 its first or distal position to its second or proximal position (in the  
9 direction of the arrow 52) to uncover the foam pad 74, allowing it to  
10 expand, as illustrated in Fig. 3A. The expanded foam pad 74 exerts  
11 hemostatic pressure upon the fatty tissue layer 56, as described  
12 previously. The locator tube (not shown) passes through and is  
13 withdrawn from the pad channel 76 formed axially in the foam pad 74.  
14 If deemed desirable by the practitioner, a coagulant agent such as  
15 collagen, thrombin or protamine may be delivered to the vicinity of the  
16 puncture site through the pad channel 76 which communicates with the  
17 catheter axial lumen 36. Alternatively, the foam pad 74 may be  
18 saturated with the agent prior to deployment.

19 The method employed with the apparatus described above may  
20 also use a guidewire 78 (Fig. 4) to perform the locating functions  
21 provided by the locator tube 30 in the previous embodiments. All three  
22 of the compression elements, viz., the compression balloon 42, the  
23 expandable prong element 66 and the foam pad 74, may be utilized  
24 with the guidewire 78. For purposes of illustration, Figs. 4 through 4F,  
25 showing only the compression balloon 42 alternative, may be viewed  
26 with the understanding that the method to be described in conjunction  
27 therewith applies to all three guidewire 78 embodiments.

1 Referring now to Fig. 4A, the introducer 12 is shown as it  
2 remains in the puncture 20 after a vascular access procedure. A  
3 conventional surgical guidewire 78 is extended through the introducer  
4 12 so that its distal end 82 extends into the lumen of the vessel 18. The  
5 dual lumen catheter 32 is passed over the guidewire 78 so that a first  
6 lumen 36 (Fig. 1D) of the catheter 32 receives the guidewire 78. The  
7 guidewire 78 maintains alignment of the catheter 32 with the puncture  
8 20 and allows re-access into the vessel 18 if it becomes necessary. As  
9 described earlier, the catheter 32, having an inflatable compression  
10 balloon 42 at its distal end 34, is inserted fully into the introducer 12  
11 until its distal end 34, including the uninflated compression balloon 42,  
12 is enclosed within the working channel 26 at the distal end 22 of the  
13 introducer 12, as shown in Fig.4B.

14 A radiopaque contrast medium (not shown) is introduced into  
15 the catheter first lumen 36, as illustrated in Fig. 4. A main leg 88 of a  
16 conventional hemostasis "Y" 86 may be passed over the guidewire 78  
17 and attached to the proximal end 33 of the catheter lumen 36. The  
18 contrast medium is then introduced into the catheter lumen 36 via a  
19 side port 90 of the "Y" 86, and viewed by the practitioner using  
20 conventional fluoroscopic techniques. To aid in locating the position of  
21 the catheter distal end 34, a radiopaque marker 84 may be provided at  
22 the tip of the catheter distal end 34 (Fig. 4D).

23 As the practitioner views the vascular scene under fluoroscopy,  
24 the introducer 12 with the catheter 32 is partially withdrawn in the  
25 direction of the arrow 52 from the puncture 20. Withdrawal is  
26 continued until contrast medium in the catheter lumen 36 escaping  
27 from around the guidewire 78 into the vessel 18 is observed to form an

1    extravasation cloud 85, signifying that the introducer 12 and the  
2    catheter 32 have exited the puncture 20. When the practitioner is  
3    satisfied through fluoroscopy that the catheter distal end element 34 is  
4    the preferred distance of about 5 to 15 mm from the vessel 18,  
5    withdrawal of the catheter 32 is halted, as shown in Fig. 4C.

6           The remainder of the closure procedure is essentially the same as  
7    described above after the preferred position of the catheter 32 was  
8    determined through the locator tube 30 method. The introducer 12 is  
9    moved from its first or distal position relative to the catheter 32 to its  
10   second or proximal position, to expose the uninflated compression  
11   balloon 42, as shown in Fig. 4D. The compression balloon 42 is then  
12   inflated to bear on the fatty tissue layer 56 as shown in Fig. 4E. The  
13   locating means (in this embodiment guidewire 78) is then withdrawn  
14   from the apparatus after an initial period of clotting (Fig. 4F). As  
15   noted previously, the method employing the guidewire 78 may be  
16   effectively adapted for use with the expandable prong element and  
17   foam tip embodiments of the present invention.

18           Still another method of the invention is illustrated in Fig. 5,  
19   wherein the apparatus 110 differs from the apparatus 10 in that the  
20   introducer 112 and the catheter 132 are not luer-locked together.  
21   Figure 5 shows the position of the catheter 132 aligned with a visible  
22   marker band 57 on the locator tube 30, just as in the first embodiment  
23   described above. It will be readily understood that the method of this  
24   "luerless" apparatus 110 may be equally utilized with the guidewire 78  
25   as with the locator tube 30 for the compression balloon embodiment of  
26   this invention.

27           When the preferred location of the expanded compression

1 balloon 42 has been achieved as shown in Fig. 5, by applying either the  
2 guidewire or the locator tube methods previously explained, force must  
3 be applied from above to the compression balloon 42 to maintain  
4 hemostatic pressure on the fatty tissue layer 56. The practitioner  
5 advances the introducer 112 downward in the direction of the arrow 62  
6 until the introducer distal end 22 makes contact with the surface of the  
7 compression balloon 42. This hemostatic pressure is then maintained  
8 by securing the introducer sheath cuff 60 to the skin patch 58 via the  
9 fastener strips or bands 64. It will be noted that no downward pressure  
10 is being exerted on the catheter 132 itself, since it has no mechanical  
11 interlock with the introducer 112, as in the previous described  
12 embodiments.

13       Although certain exemplary embodiments of the invention have  
14 been described hereinabove, it will be appreciated that a number of  
15 variations and modifications may suggest themselves to those skilled in  
16 the pertinent arts. For example, a coagulant agent may be applied to  
17 any of the above-described compression elements. Such variations and  
18 modifications are considered within the spirit and scope of the  
19 invention as defined in the claims that follow.

**1 WHAT IS CLAIMED IS:**

**2 1. A device for promoting hemostasis in a blood vessel**  
**3 puncture by compressing the subcutaneous tissue adjacent the puncture,**  
**4 wherein the puncture is accessed subcutaneously through an incision by**  
**5 an introducer disposed within the incision, the introducer having a**  
**6 proximal portion disposed externally to the skin surface, a distal end**  
**7 initially positionable within the puncture, and an axial channel**  
**8 therebetween, the device comprising:**

**9 a catheter dimensioned to be received within the axial**  
**10 channel and having an axial lumen communicating with an open**  
**11 distal end, the introducer being axially movable relative to the**  
**12 catheter between a distal position and a proximal position, the**  
**13 distal end of the catheter being enclosed within the introducer**  
**14 when the introducer is in its distal position, and being exposed to**  
**15 the subcutaneous tissue distally from the distal end of the**  
**16 introducer when the introducer is moved to its proximal position;**

**17 an elongate, flexible locator member extending through the**  
**18 catheter lumen and the distal end of the catheter and having a**  
**19 distal portion extensible into the interior of the vessel through**  
**20 the puncture; and**

**21 an expansible compression element attached to the distal**  
**22 end of the catheter, the compression element having a collapsed**  
**23 position when the distal end of the catheter is enclosed, and an**  
**24 expanded position when the distal end of the catheter is exposed;**

**25 whereby the compression element, in its expanded position,**  
**26 is deployable so as to compress the subcutaneous tissue adjacent**  
**27 the puncture, thereby to promote hemostasis at the puncture.**

1           2.     The device of Claim 1, wherein the axial lumen of the  
2 catheter is a first catheter lumen, wherein the catheter includes a  
3 second axial lumen, and wherein the compression element comprises:  
4                 an inflatable element in fluid communication with the  
5 second catheter lumen and inflatable by a fluid introduced  
6 through the second lumen, the compression element being in its  
7 collapsed position when the inflatable element is uninflated and  
8 in its expanded position when the inflatable element is inflated.

9           3.     The device of Claim 1, wherein the compression element  
10 comprises an assembly of collapsible prongs, each having a proximal  
11 end attached to the distal end of the catheter, and a distal end attached  
12 to a resilient spanning sheet, the compression element being in its  
13 collapsed position when the prong assembly is collapsed radially  
14 inwardly, and in its expanded position when the prong assembly is  
15 expanded radially outwardly.

16           4.     The device of Claim 1, wherein the compression element  
17 comprises a resilient foam pad attached to the distal end of the catheter  
18 and having a collapsed position when the distal end of the catheter is  
19 enclosed, and an expanded position when the distal end of the catheter  
20 is exposed.

21           5.     The device of Claim 1, wherein the locator member  
22 comprises:  
23                 a hollow locator tube disposed axially through the catheter  
24 lumen so as to extend through the distal end of the catheter and  
25 having a distal portion extensible into the interior of the vessel  
26 through the puncture; and

27                 a locating balloon disposed at the distal portion of the

1 locator tube and inflatable through the locator tube when  
2 positioned in the interior of the vessel.

3 6. The device of Claim 1, wherein the locator member  
4 comprises:

5 an elongate guide wire disposed axially through the  
6 catheter lumen so as to extend through the distal end of the  
7 catheter and into the interior of the vessel through the puncture.

8 7. The device of Claim 2, wherein the locator member  
9 comprises:

10 a hollow locator tube disposed axially through the first  
11 catheter lumen so as to extend through the distal end of the  
12 catheter and having a distal portion extensible into the interior of  
13 the vessel through the puncture; and

14 a locating balloon disposed at the distal portion of the  
15 locator tube and inflatable through the locator tube when  
16 positioned in the interior of the vessel.

17 8. The device of Claim 2, wherein the locator member  
18 comprises:

19 an elongate guide wire disposed axially through the first  
20 catheter lumen so as to extend through the distal end of the  
21 catheter and into the interior of the vessel through the puncture.

22 9. The device of Claim 3, wherein the spanning sheet includes  
23 an aperture, and wherein the locator member comprises:

24 a hollow locator tube disposed axially through the catheter  
25 lumen so as to extend through the distal end of the catheter and  
26 the spanning sheet aperture, and having a distal portion  
27 extensible into the interior of the vessel through the puncture;



1           and

2                   a locating balloon disposed at the distal portion of the  
3           locator tube and inflatable through the locator tube when  
4           positioned in the interior of the vessel.

5           10.   The device of Claim 3, wherein the spanning sheet includes  
6   an aperture, and wherein the locator member comprises:

7                   an elongate guide wire disposed axially through the  
8           catheter lumen so as to extend through the distal end of the  
9           catheter and the spanning sheet aperture into the interior of the  
10          vessel through the puncture.

11          11.   The device of Claim 4, wherein the foam pad includes an  
12   axial passage, and wherein the locator member comprises:

13                   a hollow locator tube disposed axially through the catheter  
14           lumen so as to extend through the distal end of the catheter and  
15           the axial passage in the foam pad, the locator tube having a distal  
16           portion extensible into the interior of the vessel through the  
17           puncture; and

18                   a locating balloon disposed at the distal portion of the  
19           locator tube and inflatable through the locator tube when  
20           positioned in the interior of the vessel.

21          12.   The device of Claim 4, wherein the foam pad includes an  
22   axial passage, and wherein the locator member comprises:

23                   an elongate guide wire disposed axially through the  
24           catheter lumen so as to extend through the distal end of the  
25           catheter and the axial passage in the foam pad, the guide wire  
26           having a distal portion extensible into the interior of the vessel  
27           through the puncture.

- 1        13.    The device of Claim 1, further comprising:  
2                a radiopaque marker at the distal end of the catheter; and  
3                means for introducing a contrast medium into the catheter  
4                lumen.
- 5        14.    The device of Claim 2, further comprising:  
6                a radiopaque marker at the distal end of the catheter; and  
7                means for introducing a contrast medium into the first  
8                catheter lumen.
- 9        15.    The device of Claim 1, further comprising:  
10               pressure applying means, engageable with the external  
11               portion of the introducer, for applying a downward force to the  
12               introducer when the catheter is disposed within the axial channel  
13               of the introducer.
- 14       16.    The device of Claim 15, wherein the catheter is connected  
15       to the introducer so that the downward force is applied to both the  
16       introducer and the catheter.
- 17       17.    The device of Claim 15, wherein the pressure applying  
18       means comprises:  
19               a clamping device secured to the external portion of the  
20               introducer; and  
21               a skin patch secured to the clamping device and adhesively  
22               attachable to the surface of the skin.
- 23       18.    The device of Claim 16, wherein the pressure applying  
24       means comprises:  
25               a clamping device secured to the external portion of the  
26               introducer; and  
27               a skin patch secured to the clamping device and adhesively

1           attachable to the surface of the skin.

2           19.   A device for promoting hemostasis in a blood vessel  
3   puncture by compressing the subcutaneous tissue adjacent the puncture,  
4   wherein the puncture is accessed subcutaneously through an incision by  
5   an introducer disposed within the incision, the introducer having a  
6   proximal end disposed externally to the skin surface, a distal end  
7   initially positionable within the puncture, and an axial channel  
8   therebetween, the device comprising:

9           a catheter dimensioned to be received within the axial  
10   channel and having a first axial lumen communicating with an  
11   open distal end and a second axial lumen, the introducer being  
12   axially movable relative to the catheter between a distal position  
13   and a proximal position, the distal end of the catheter being  
14   enclosed within the introducer when the introducer is in its distal  
15   position, and being exposed to the subcutaneous tissue distally  
16   from the distal end of the introducer when the introducer is  
17   moved to its proximal position; and

18           an inflatable compression element attached to the distal  
19   end of the catheter and in fluid communication with the second  
20   lumen so as to be inflatable with a fluid introduced through the  
21   second lumen when the distal end of the catheter is exposed;

22           whereby the compression element, when inflated, is  
23   deployable so as to compress the subcutaneous tissue adjacent  
24   the puncture, thereby to promote hemostasis at the puncture.

25           20.   The device of Claim 19, further comprising:

26           an elongate, flexible locator member extending through the  
27   first catheter lumen and the distal end of the catheter, and

1       having a distal portion extensible into the interior of the vessel  
2       through the puncture.

3       21.   The device of Claim 20, wherein the locator member  
4       comprises:

5               a hollow locator tube disposed axially through the first  
6       catheter lumen so as to extend through the distal end of the  
7       catheter and having a distal portion extensible into the interior of  
8       the vessel through the puncture; and

9               a locating balloon disposed at the distal portion of the  
10      locator tube and inflatable through the locator tube when  
11      positioned in the interior of the vessel.

12      22.   The device of Claim 20, wherein the locator member  
13      comprises:

14              an elongate guide wire disposed axially through the first  
15      catheter lumen so as to extend through the distal end of the  
16      catheter and into the interior of the vessel through the puncture.

17      23.   The device of Claim 19, further comprising:

18              a radiopaque marker at the distal end of the catheter; and  
19              means for introducing a contrast medium into the first  
20      catheter lumen.

21      24.   The device of Claim 19, further comprising:

22              pressure applying means, engageable with the external  
23      portion of the introducer, for applying a downward force to the  
24      introducer when the catheter is disposed within the axial channel  
25      of the introducer.

26      25.   The device of Claim 24, wherein the catheter is connected  
27      to the introducer so that the downward force is applied to both the

1 introducer and the catheter.

2       26. The device of Claim 24, wherein the pressure applying  
3 means comprises:

4           a clamping device secured to the external portion of the  
5 introducer; and

6           a skin patch secured to the clamping device and adhesively  
7 attachable to the surface of the skin.

8       27. The device of Claim 25, wherein the pressure applying  
9 means comprises:

10           a clamping device secured to the external portion of the  
11 introducer; and

12           a skin patch secured to the clamping device and adhesively  
13 attachable to the surface of the skin.

14       28. A device for promoting hemostasis in a blood vessel  
15 puncture by compressing the subcutaneous tissue adjacent the puncture,  
16 wherein the puncture is accessed subcutaneously through an incision by  
17 an introducer disposed within the incision, the introducer having a  
18 proximal end disposed externally to the skin surface, a distal end  
19 initially positionable within the puncture, and an axial channel  
20 therebetween, the device comprising:

21           a catheter dimensioned to be received within the axial  
22 channel and having an axial lumen communicating with an open  
23 distal end, the introducer being axially movable relative to the  
24 catheter between a distal position and a proximal position, the  
25 distal end of the catheter being enclosed within the introducer  
26 when the introducer is in its distal position, and being exposed to  
27 the subcutaneous tissue distally from the distal end of the

1 introducer when the introducer is moved to its proximal position;  
2 and

3 an assembly of collapsible prongs, each having a proximal  
4 end attached to the distal end of the catheter and a distal end  
5 attached to a spanning sheet, the prong assembly having a  
6 radially inwardly collapsed position when the distal end of the  
7 catheter is enclosed, and a radially outwardly expanded position  
8 when the distal end of the catheter is exposed;

9 whereby the prong assembly, in its expanded position, is  
10 deployable so as to compress the subcutaneous tissue adjacent  
11 the puncture, thereby to promote hemostasis at the puncture.

12 29. The device of Claim 28, wherein the spanning sheet  
13 includes an aperture, the device further comprising:

14 an elongate, flexible locator member extensible through  
15 the catheter lumen, the distal end of the catheter, and the  
16 spanning sheet aperture, and having a distal portion extensible  
17 into the interior of the vessel through the puncture.

18 30. The device of Claim 29, wherein the locator member  
19 comprises:

20 a hollow locator tube extensible axially through the  
21 catheter lumen so as to extend through the distal end of the  
22 catheter and the spanning sheet aperture, and having a distal  
23 portion extensible into the interior of the vessel through the  
24 puncture; and

25 a locating balloon disposed at the distal portion of the  
26 locator tube and inflatable through the locator tube when  
27 positioned in the interior of the vessel.

1        31. The device of Claim 29, wherein the locator member  
2 comprises:

3            an elongate guide wire extensible axially through the  
4 catheter lumen so as to extend through the distal end of the  
5 catheter and the spanning sheet aperture, and into the interior of  
6 the vessel through the puncture.

7        32. The device of Claim 28, further comprising:

8            a radiopaque marker at the distal end of the catheter; and  
9            means for introducing a contrast medium into the catheter  
10 lumen.

11       33. The device of Claim 28, further comprising:

12           pressure applying means, engageable with the external  
13 portion of the introducer, for applying a downward force to the  
14 introducer when the catheter is disposed within the axial channel  
15 of the introducer.

16       34. The device of Claim 33, wherein the catheter is connected  
17 to the introducer so that the downward force is applied to both the  
18 introducer and the catheter.

19       35. The device of Claim 33, wherein the pressure applying  
20 means comprises:

21           a clamping device secured to the external portion of the  
22 introducer; and

23           a skin patch secured to the clamping device and adhesively  
24 attachable to the surface of the skin.

25       36. The device of Claim 34, wherein the pressure applying  
26 means comprises:

27           a clamping device secured to the external portion of the



35.

1           introducer; and

2                   a skin patch secured to the clamping device and adhesively  
3           attachable to the surface of the skin.

4           37.   A device for promoting hemostasis in a blood vessel  
5   puncture by compressing the subcutaneous tissue adjacent the puncture,  
6   wherein the puncture is accessed subcutaneously through an incision by  
7   an introducer disposed within the incision, the introducer having a  
8   proximal end disposed externally to the skin surface, a distal end  
9   initially positionable within the puncture, and an axial channel  
10   therebetween, the device comprising:

11                   a catheter dimensioned to be received within the axial  
12           channel and having an axial lumen communicating with an open  
13           distal end, the introducer being axially movable relative to the  
14           catheter between a distal position and a proximal position, the  
15           distal end of the catheter being enclosed within the introducer  
16           when the introducer is in its distal position, and being exposed to  
17           the subcutaneous tissue distally from the distal end of the  
18           introducer when the introducer is moved to its proximal position;  
19           and

20                   a resilient foam pad attached to the distal end of the  
21           catheter, the pad having a collapsed position when the distal end  
22           of the catheter is enclosed, and an expanded position when the  
23           distal end of the catheter is exposed;

24                   whereby the pad, in its expanded position, is deployable so  
25           as to compress the subcutaneous tissue adjacent the puncture,  
26           thereby to promote hemostasis at the puncture.

27           38.   The device of Claim 37, wherein the pad includes an axial

1 passage therethrough, the device further comprising:

2 an elongate, flexible locator member extensible through  
3 the catheter lumen, the distal end of the catheter and the axial  
4 passage through the pad, and having a distal portion extensible  
5 into the interior of the vessel through the puncture.

6 39. The device of Claim 38, wherein the locator member  
7 comprises:

8 a hollow locator tube extensible axially through the  
9 catheter lumen so as to extend through the distal end of the  
10 catheter and the axial passage through the pad, and having a  
11 distal portion extensible into the interior of the vessel through  
12 the puncture; and

13 a locating balloon disposed at the distal portion of the  
14 locator tube and inflatable through the locator tube when  
15 positioned in the interior of the vessel.

16 40. The device of Claim 38, wherein the locator member  
17 comprises:

18 an elongate guide wire extensible axially through the  
19 catheter lumen so as to extend through the distal end of the  
20 catheter and the axial passage through the pad, and into the  
21 interior of the vessel through the puncture.

22 41. The device of Claim 37, further comprising:

23 a radiopaque marker at the distal end of the catheter; and  
24 means for introducing a contrast medium into the catheter  
25 lumen.

26 42. The device of Claim 37, further comprising:

27 pressure applying means, engageable with the external

1 portion of the introducer, for applying a downward force to the  
2 introducer when the catheter is disposed within the axial channel  
3 of the introducer.

4 43. The device of Claim 42, wherein the catheter is connected  
5 to the introducer so that the downward force is applied to both the  
6 introducer and the catheter.

7 44. The device of Claim 42, wherein the pressure applying  
8 means comprises:

9 a clamping device secured to the external portion of the  
10 introducer; and

11 a skin patch secured to the clamping device and adhesively  
12 attachable to the surface of the skin.

13 45. The device of Claim 43, wherein the pressure applying  
14 means comprises:

15 a clamping device secured to the external portion of the  
16 introducer; and

17 a skin patch secured to the clamping device and adhesively  
18 attachable to the surface of the skin.

19 46. A method for promoting hemostasis in a blood vessel  
20 puncture that is accessed subcutaneously through an incision by an  
21 introducer disposed within the incision, the introducer having a portion  
22 disposed externally to the skin surface with an open proximal end, an  
23 open distal end initially positionable within the puncture, and an axial  
24 channel therebetween, the method comprising the steps of:

25 providing a catheter having a distal end to which is  
26 attached an expansible compression element, and passing the  
27 catheter through the introducer channel so that the compression

1 element is enclosed, in a collapsed position, near the distal end  
2 of the introducer;

3 withdrawing the introducer and the catheter together in  
4 the proximal direction a predetermined distance from the  
5 puncture, while maintaining the compression element enclosed  
6 within the introducer;

7 moving the introducer axially relative to the catheter in the  
8 proximal direction to expose the compression element from the  
9 distal end of the introducer;

10 expanding the compression element in the subcutaneous  
11 tissue between the puncture and the skin; and

12 applying pressure to the compression element to promote  
13 hemostasis at the puncture.

14 47. The method of Claim 46, further comprising the step of:

15 before the step of passing the catheter, passing an  
16 elongate, flexible locator member through the introducer channel  
17 and into the blood vessel through the distal end of the introducer  
18 and through the puncture, the catheter having an axial lumen so  
19 that, when the catheter is passed through the introducer channel,  
20 the catheter is disposed coaxially between the locator member  
21 and the introducer.

22 48. The method of Claim 47, wherein the locator member  
23 comprises a hollow locator tube having a distal portion extensible into  
24 the interior of the blood vessel through the puncture, and an inflatable  
25 locating balloon disposed at the distal portion of the tube, and wherein  
26 the step of withdrawing the catheter and the introducer includes the  
27 steps of:

1           inflating the locating balloon through the locator tube  
2           while the distal portion of the tube, including the locating  
3           balloon, is disposed within the blood vessel; and

4           withdrawing the catheter, the introducer, and the locator  
5           tube together in the proximal direction until the locating balloon  
6           lodges against the interior wall of the blood vessel.

7           49. The method of Claim 47, further comprising the steps of:  
8           after the application of pressure to the compression  
9           element for a first period of time, withdrawing the locator  
10          member from the puncture; and

11          continuing the application of pressure to the compression  
12          element for a second period of time.

13          50. The method of Claim 49, further comprising the steps of:  
14          after the second period of time has elapsed, collapsing the  
15          compression element; and

16          withdrawing the catheter and the introducer from the  
17          incision.

18          51. The method of Claim 47, wherein the locator member  
19          includes a guide wire having a distal portion extensible into the blood  
20          vessel through the puncture, and wherein the step of withdrawing  
21          includes the steps of:

22          introducing a contrast medium into the puncture through  
23          the catheter lumen; and

24          fluoroscopically viewing the contrast medium as the  
25          catheter and the introducer are withdrawn to determine when the  
26          predetermined distance from the puncture has been attained.

27          52. The method of Claim 46, wherein the step of applying

- 1 pressure to the compression element comprises the steps of:  
2 applying pressure to the external portion of the introducer;  
3 and  
4 transmitting the pressure to the compression element.
- 5 53. The method of Claim 52, wherein the transmitting step  
6 comprises the steps of:  
7 attaching the introducer to the skin surface;  
8 connecting the introducer to the catheter; and  
9 transmitting the pressure from the introducer to the  
10 catheter and then to the compression element.

FIG. 1

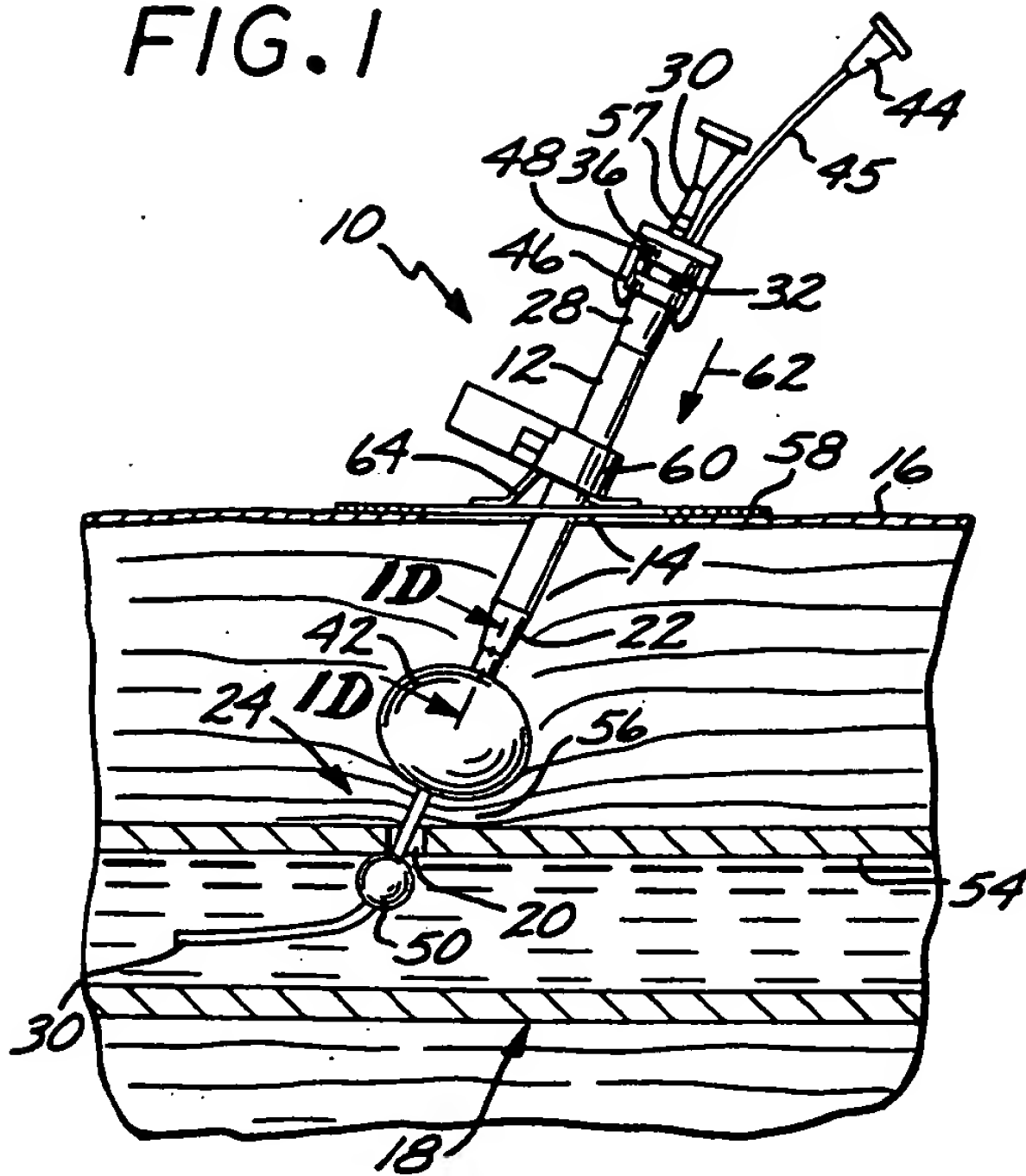


FIG. 1A

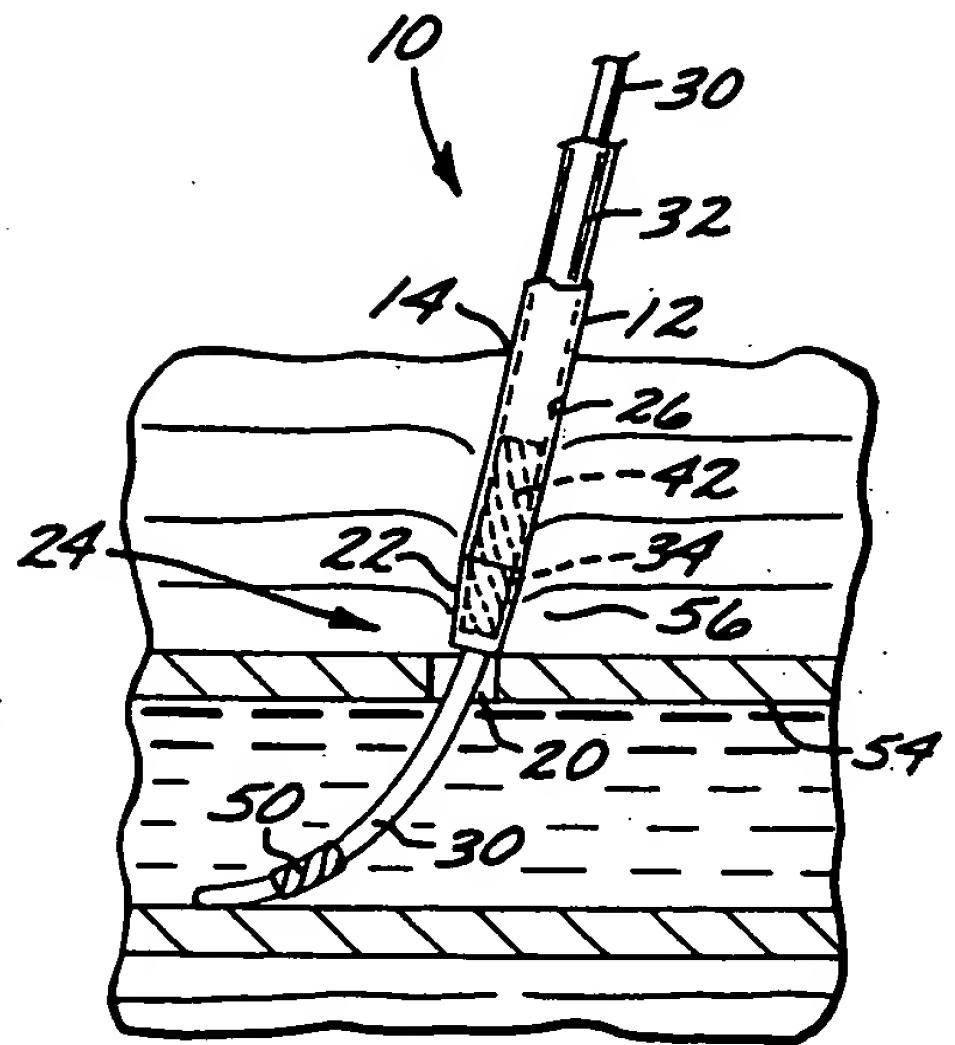


FIG. 1B

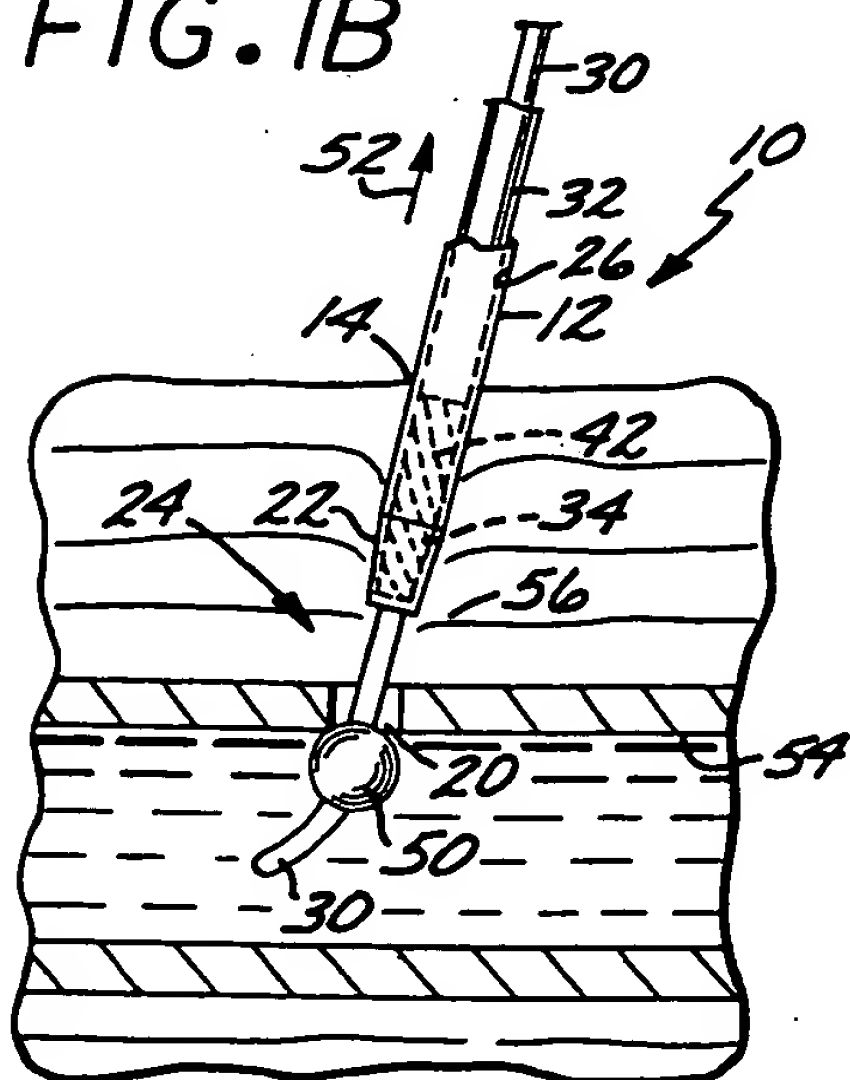
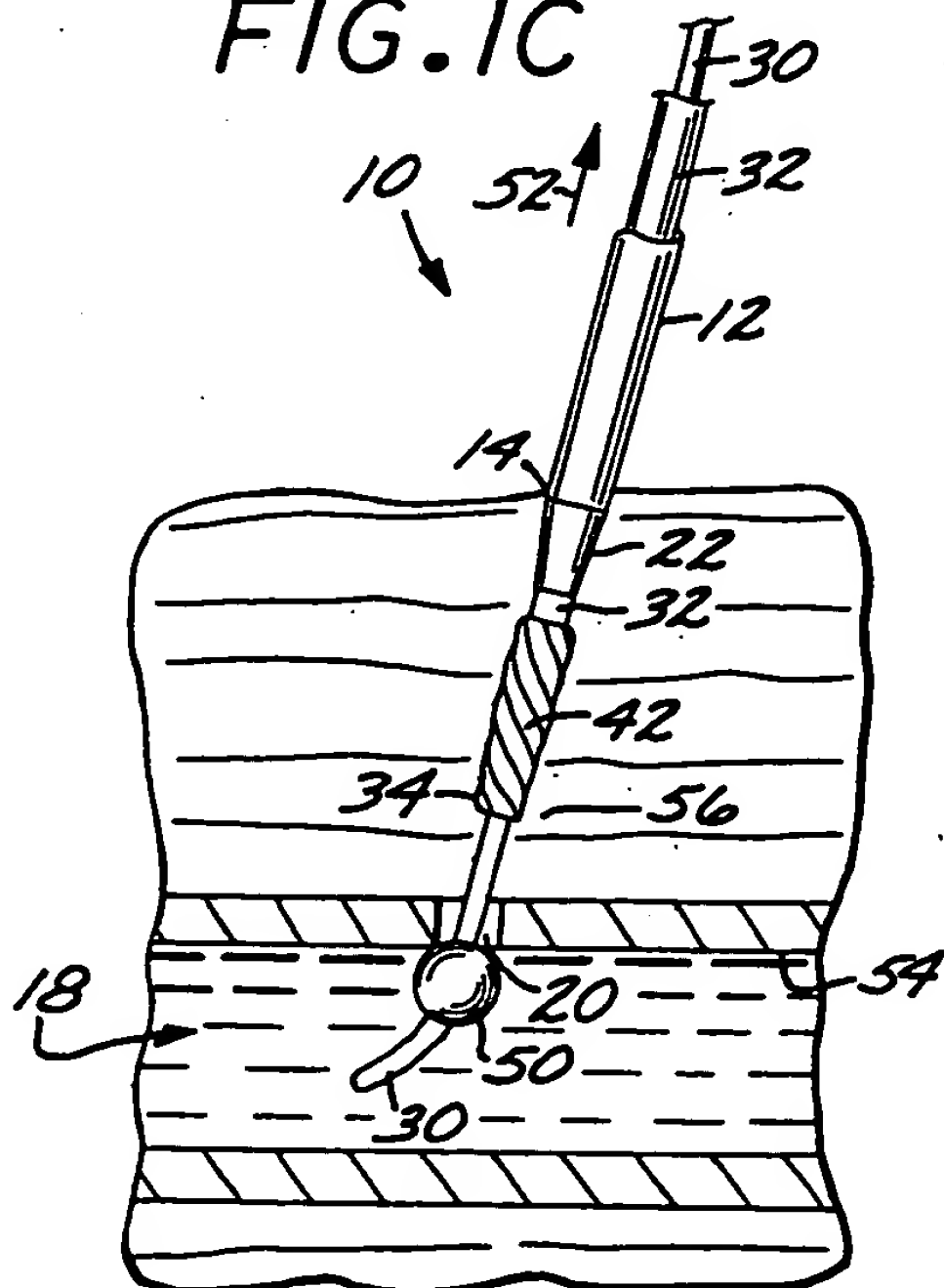


FIG. 1C







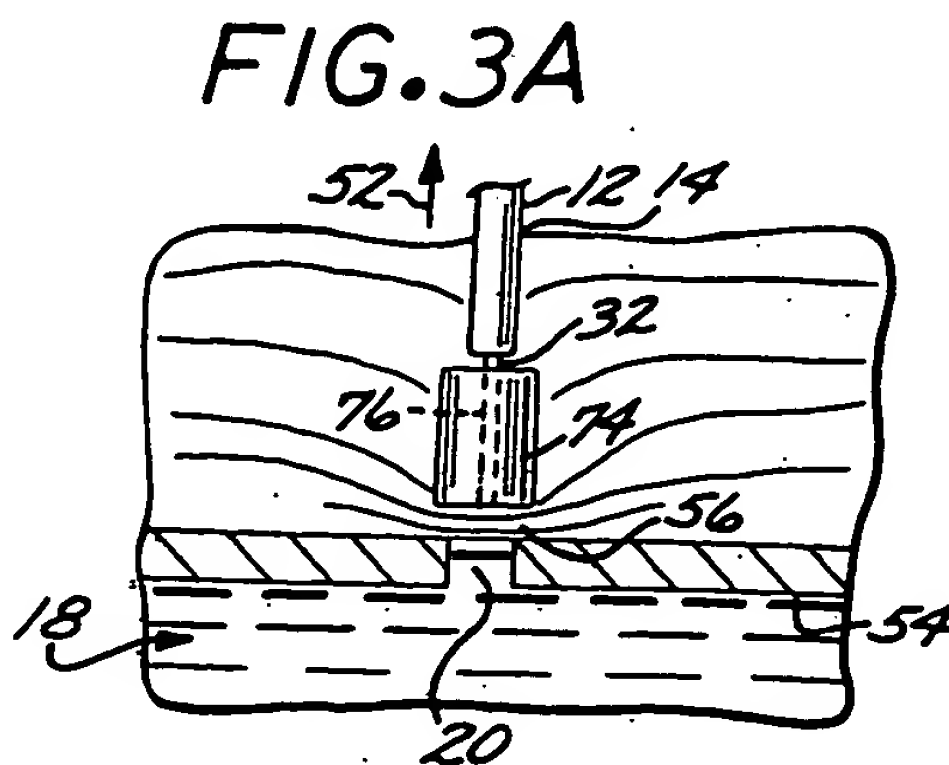
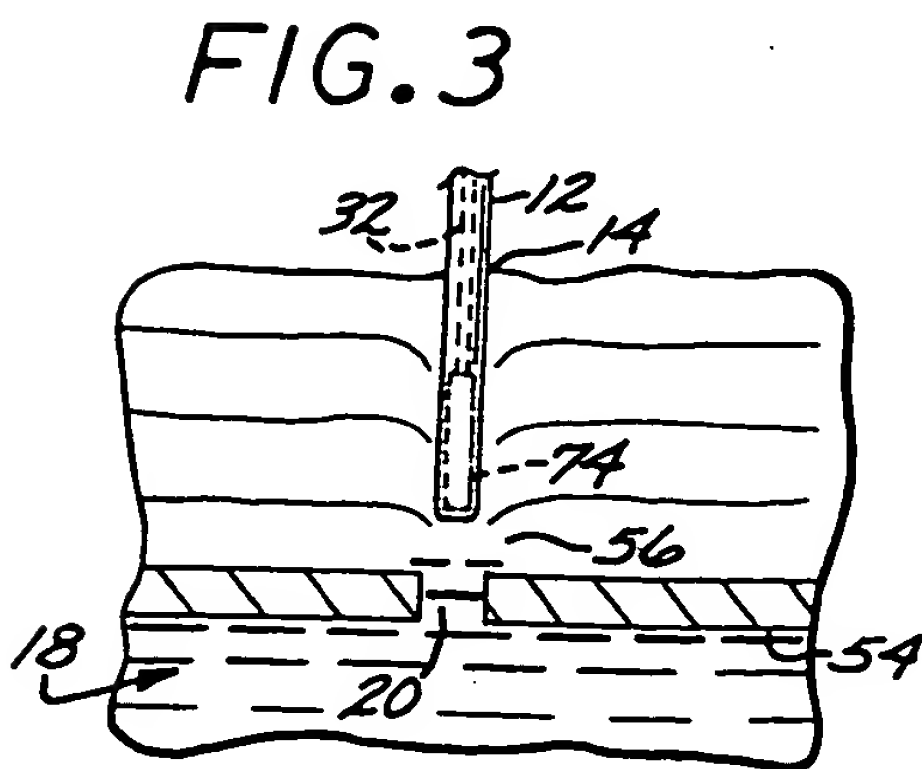
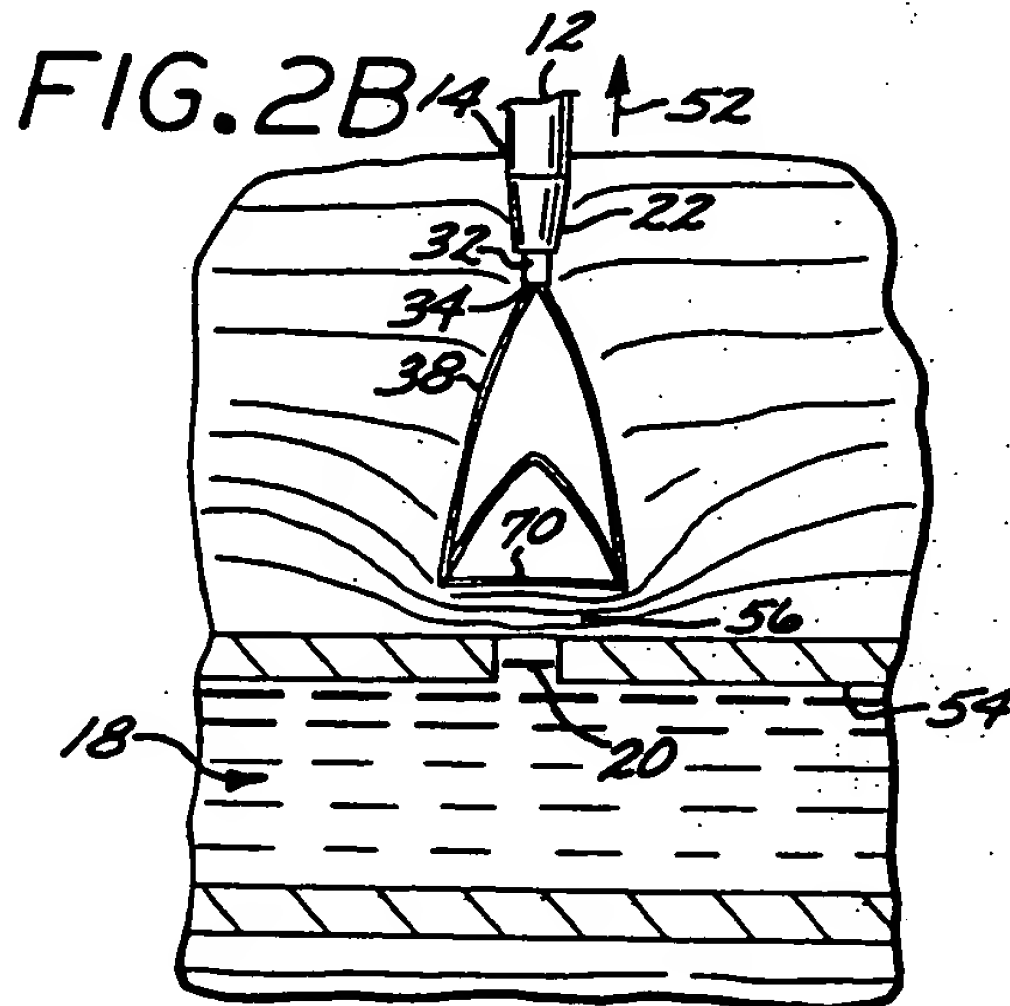
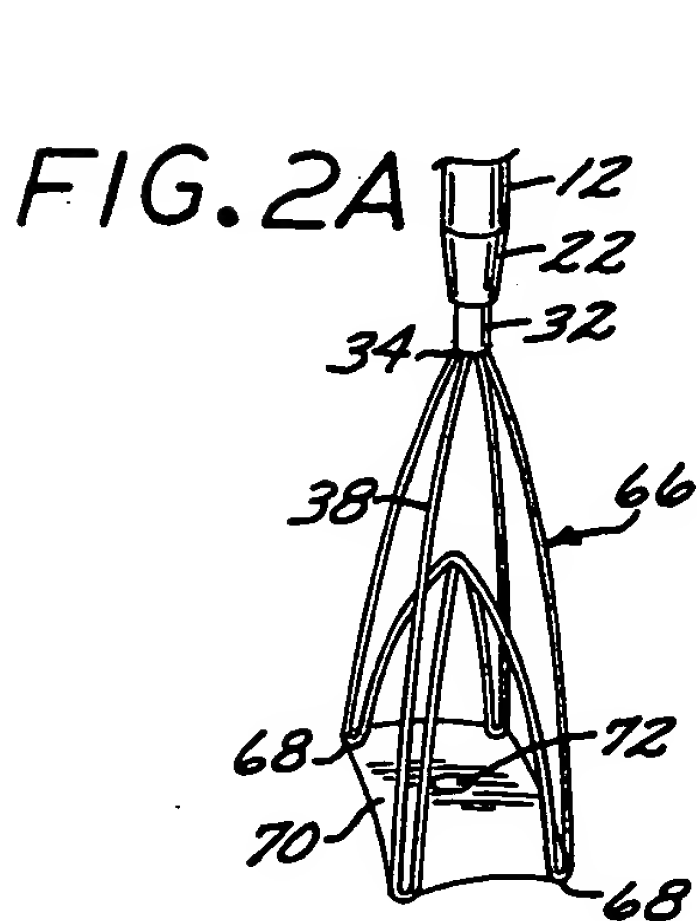
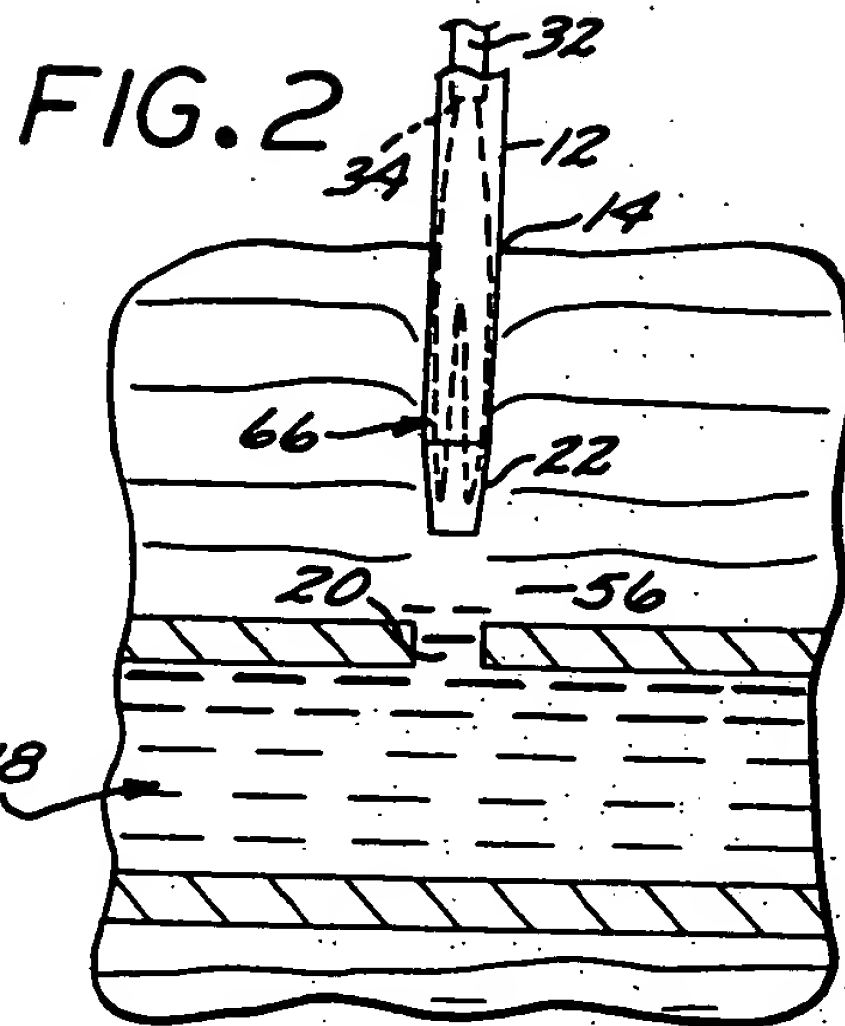
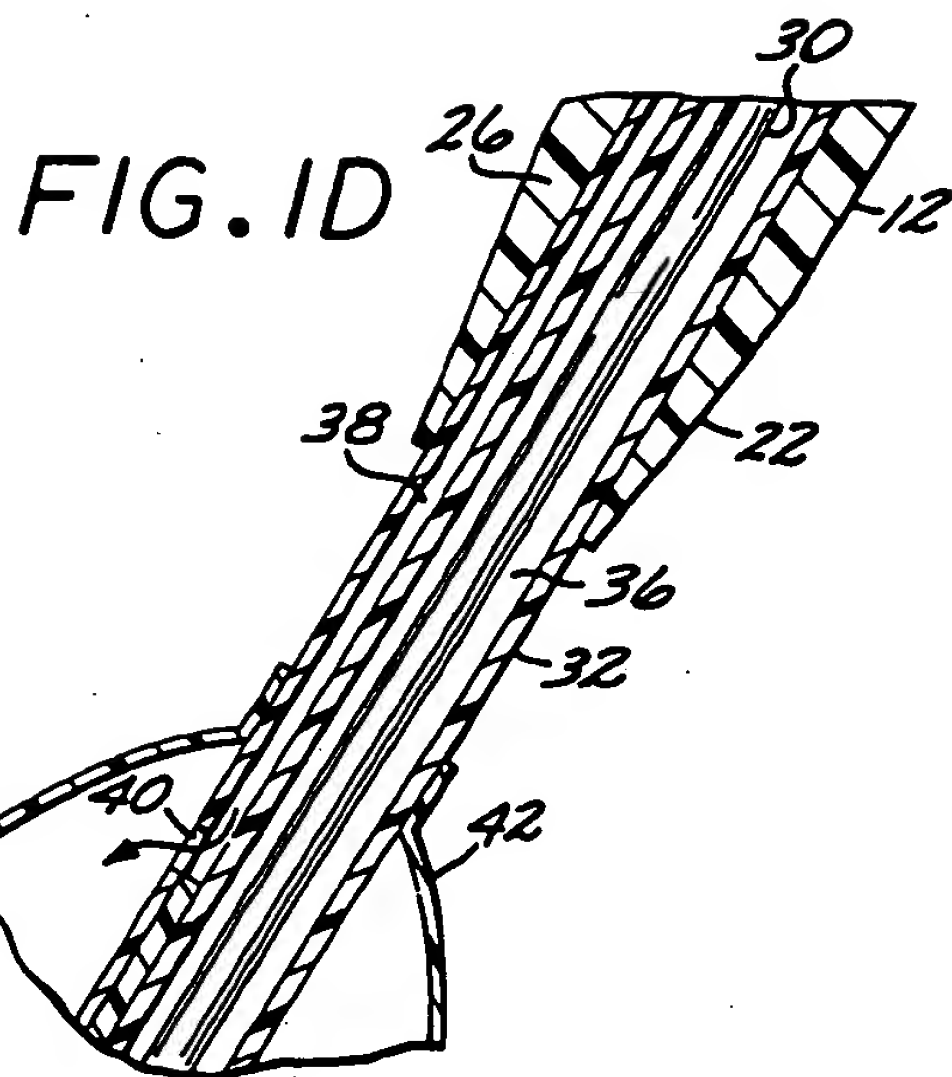




FIG. 4

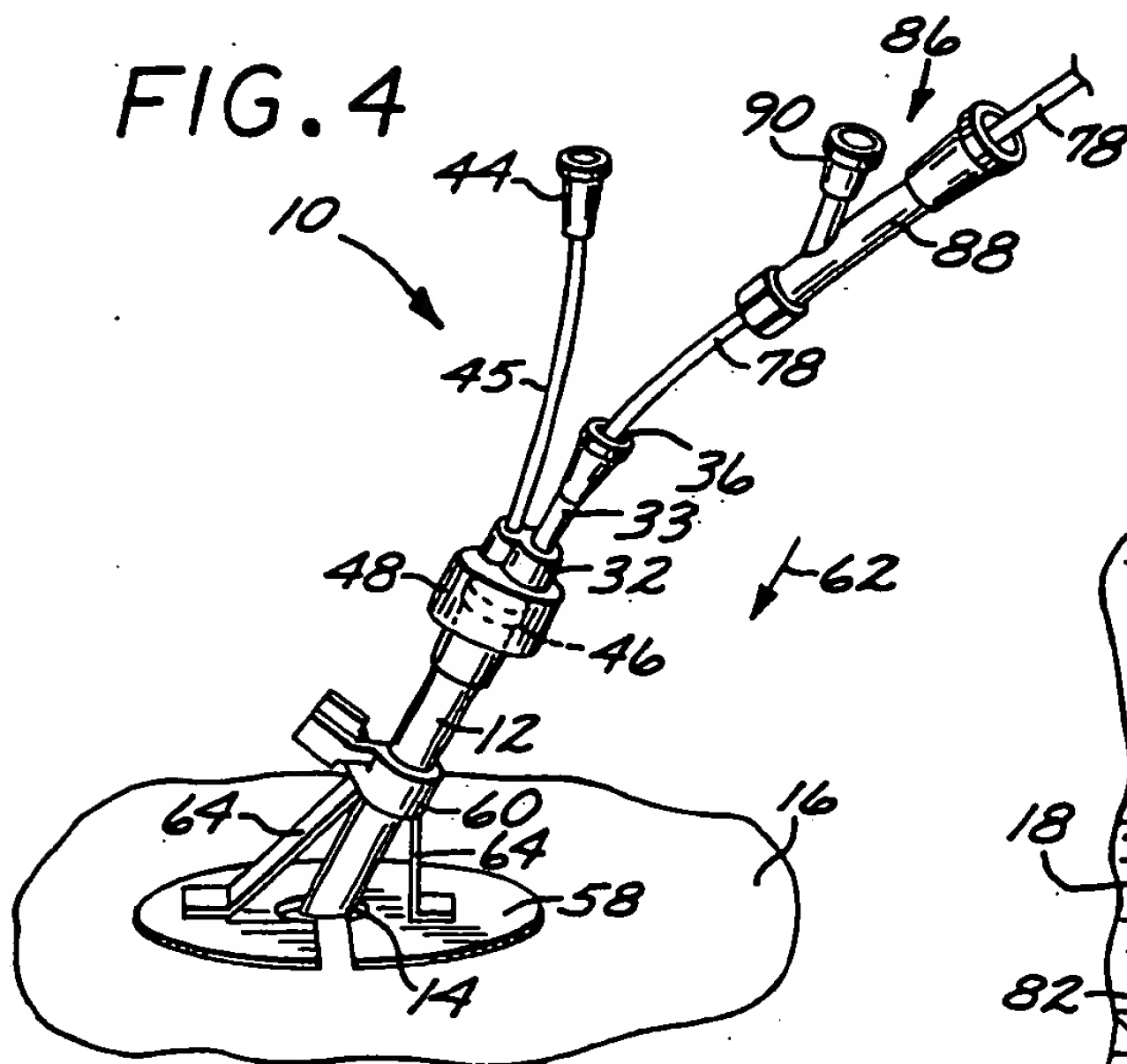


FIG. 4A

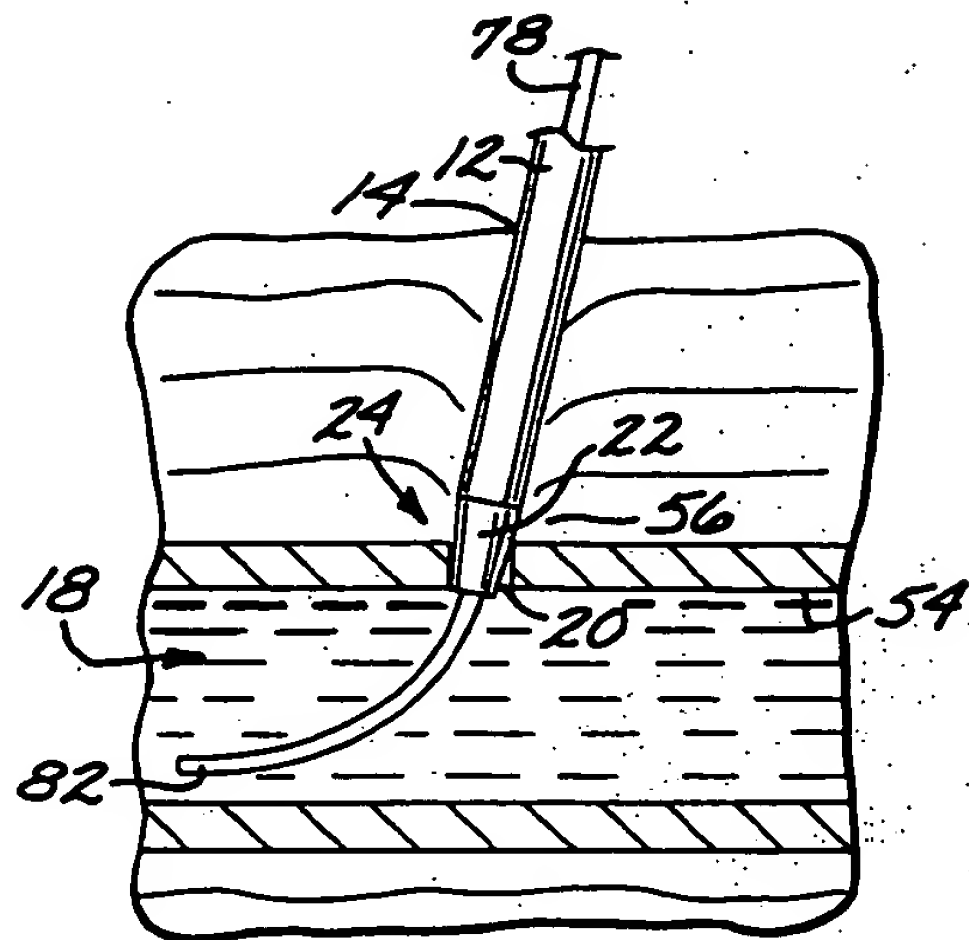


FIG. 4B

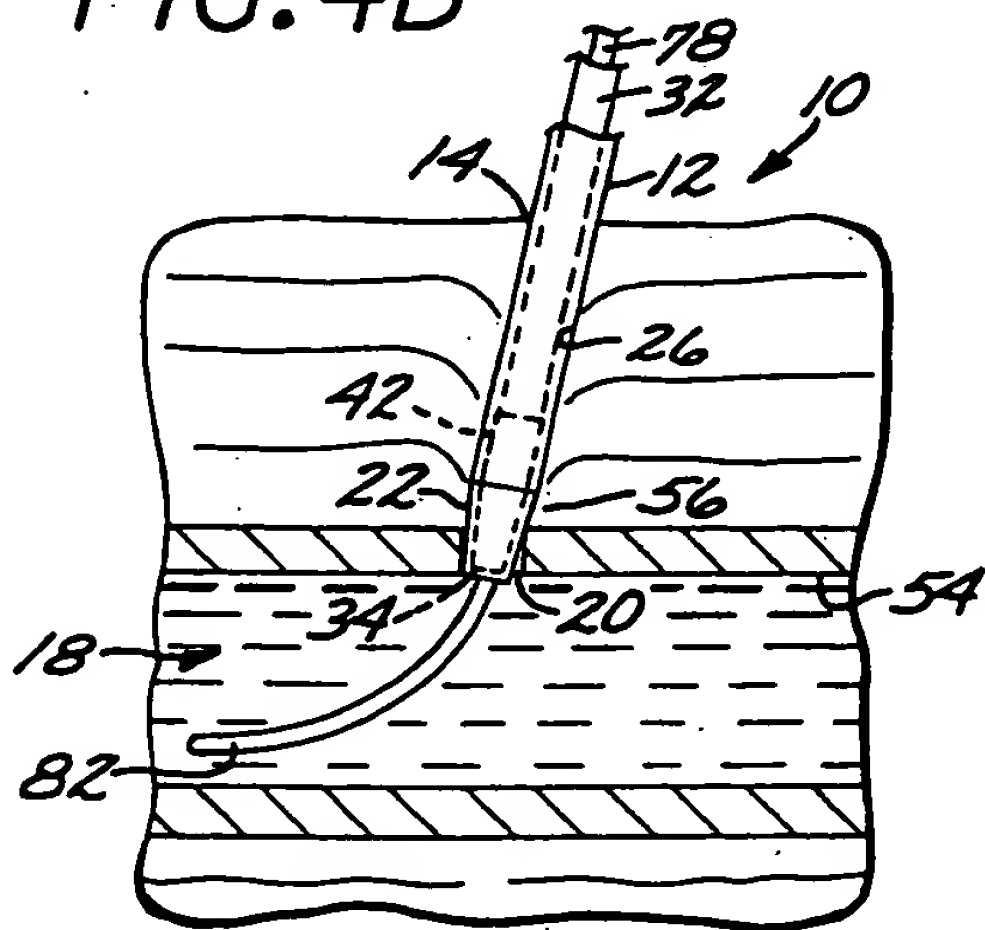


FIG. 4C

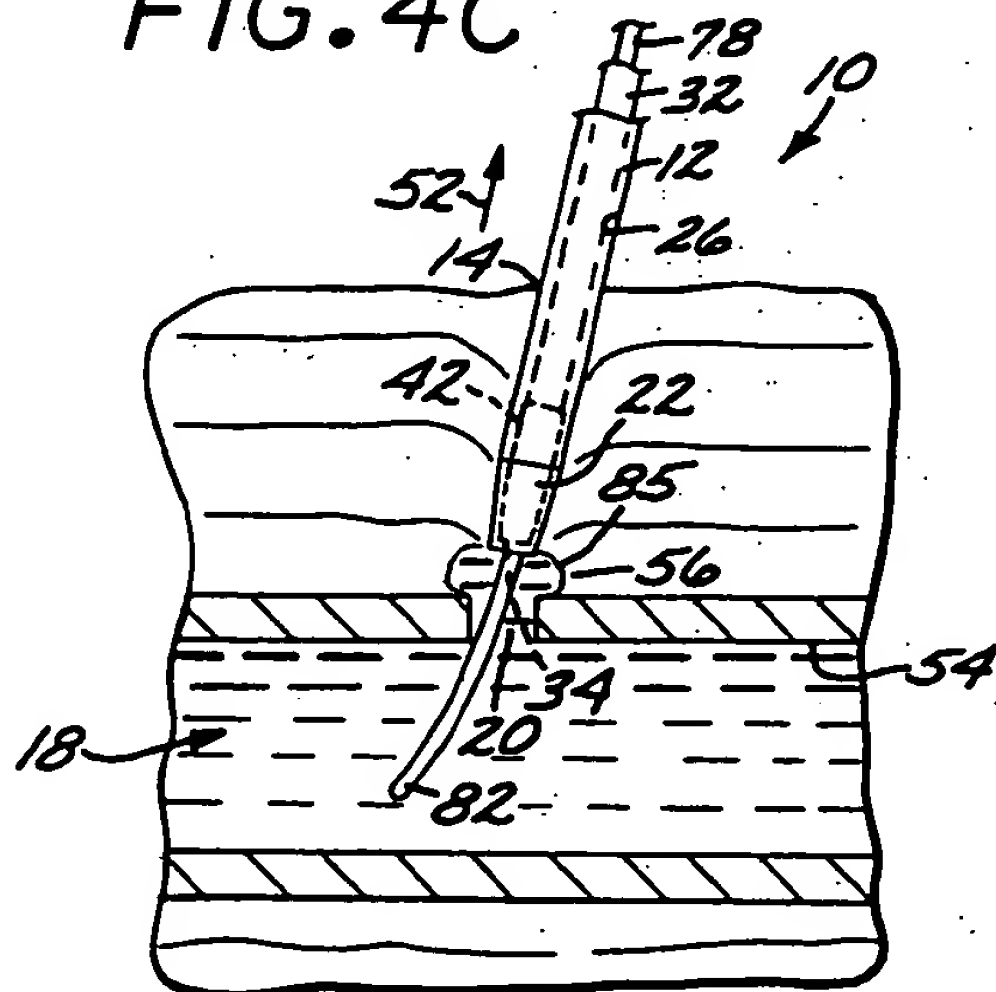


FIG. 4D

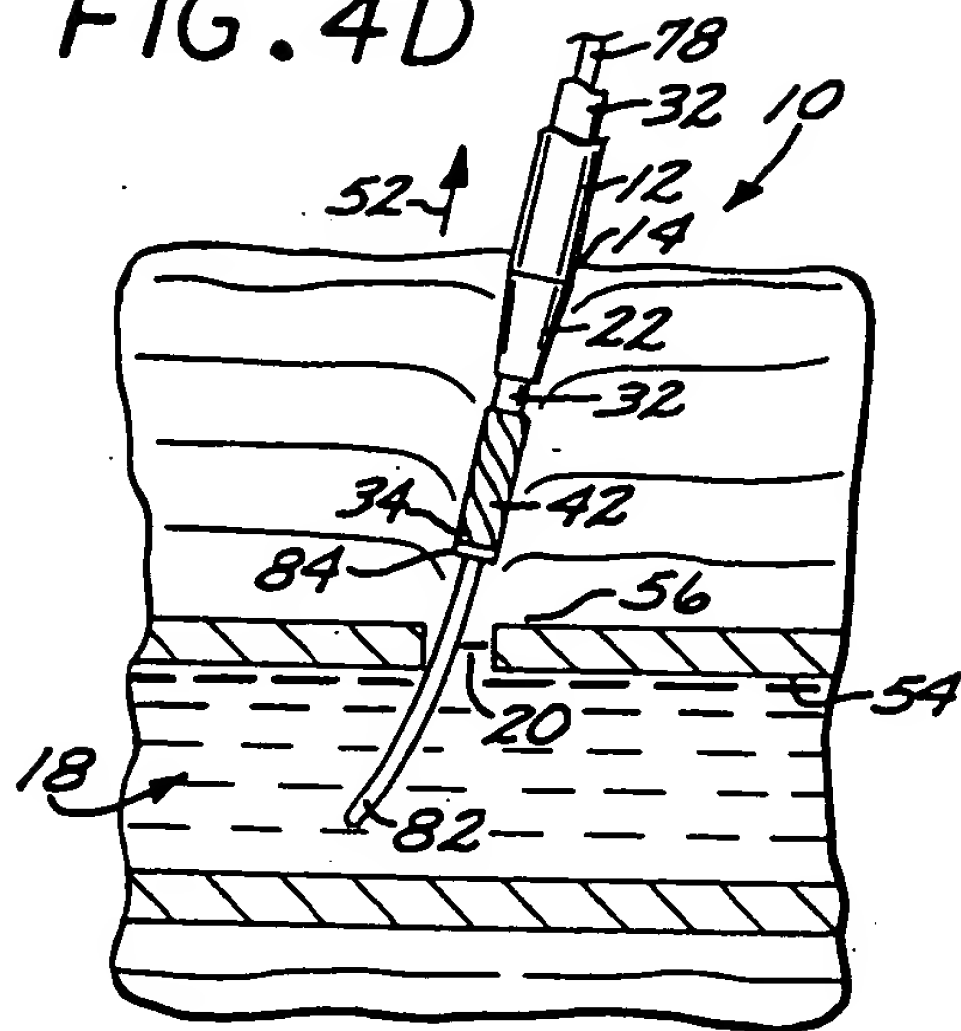


FIG. 4E

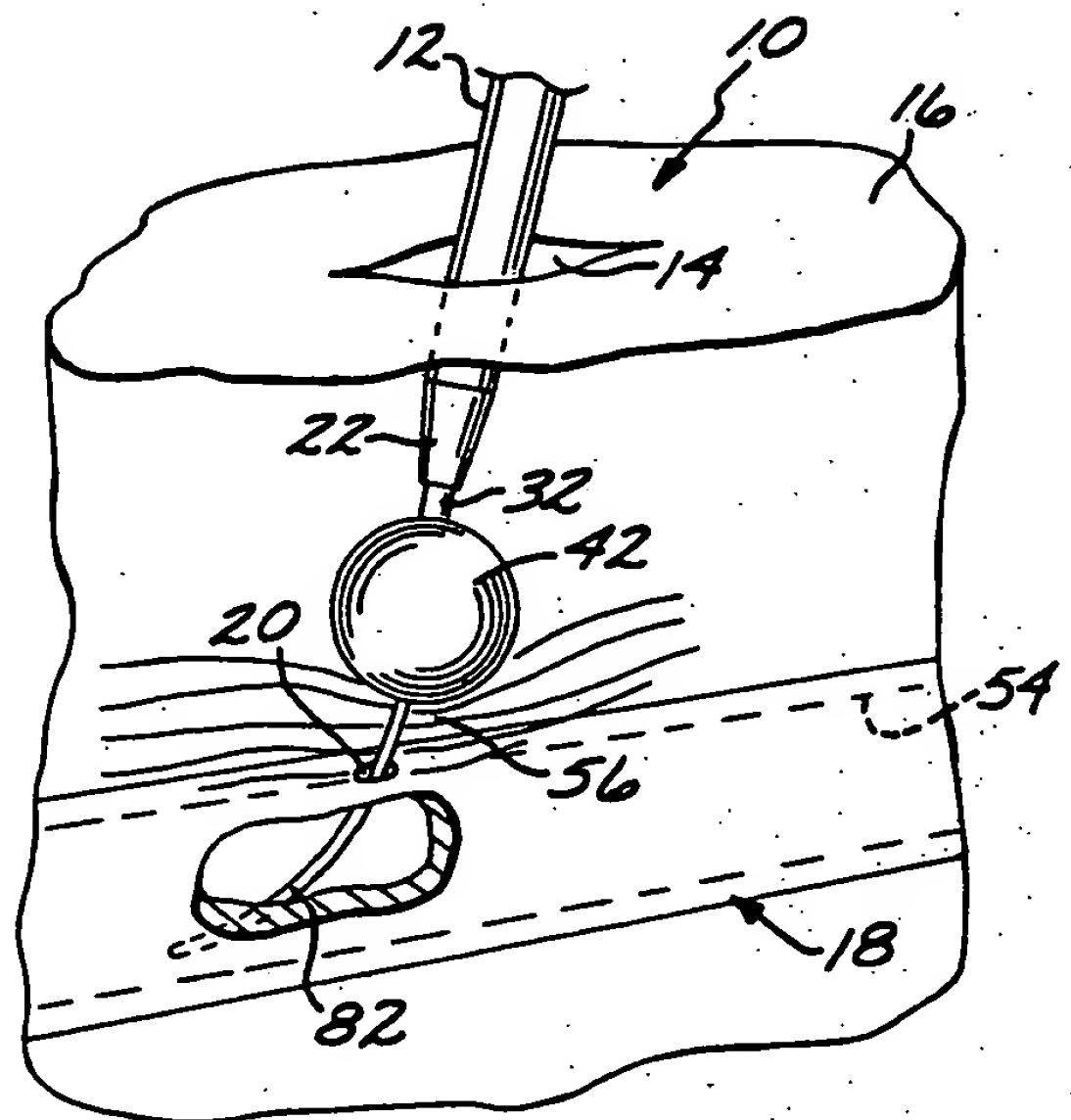


FIG. 4F

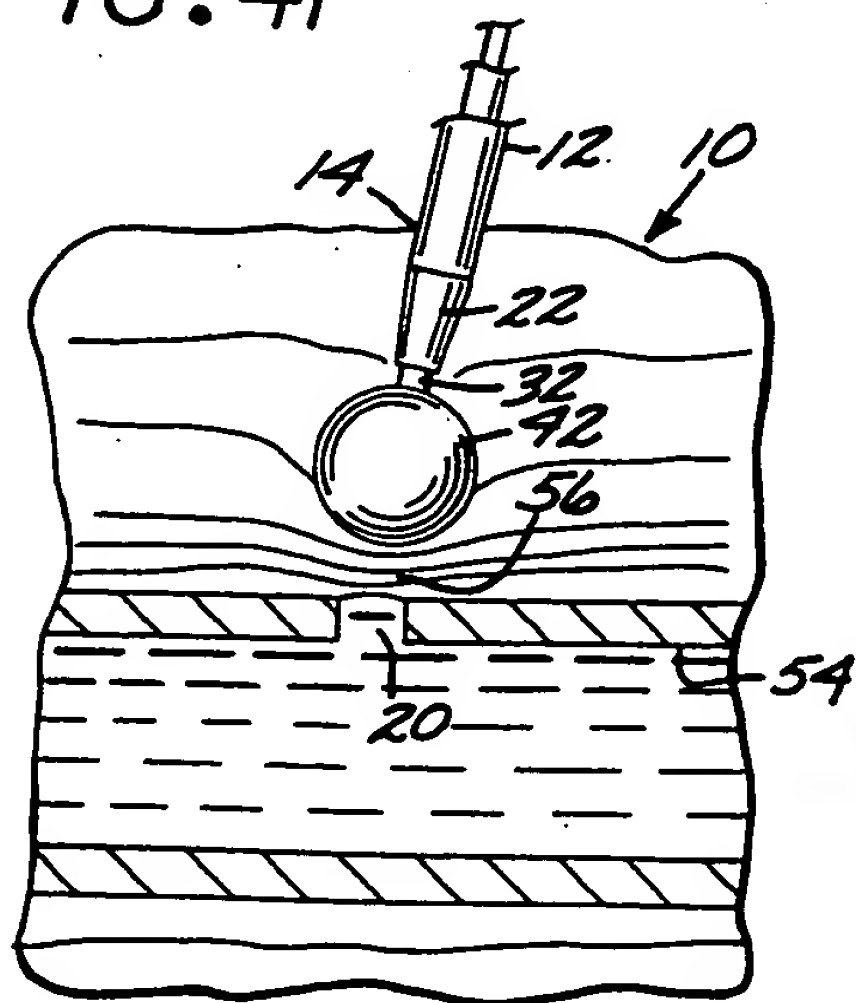
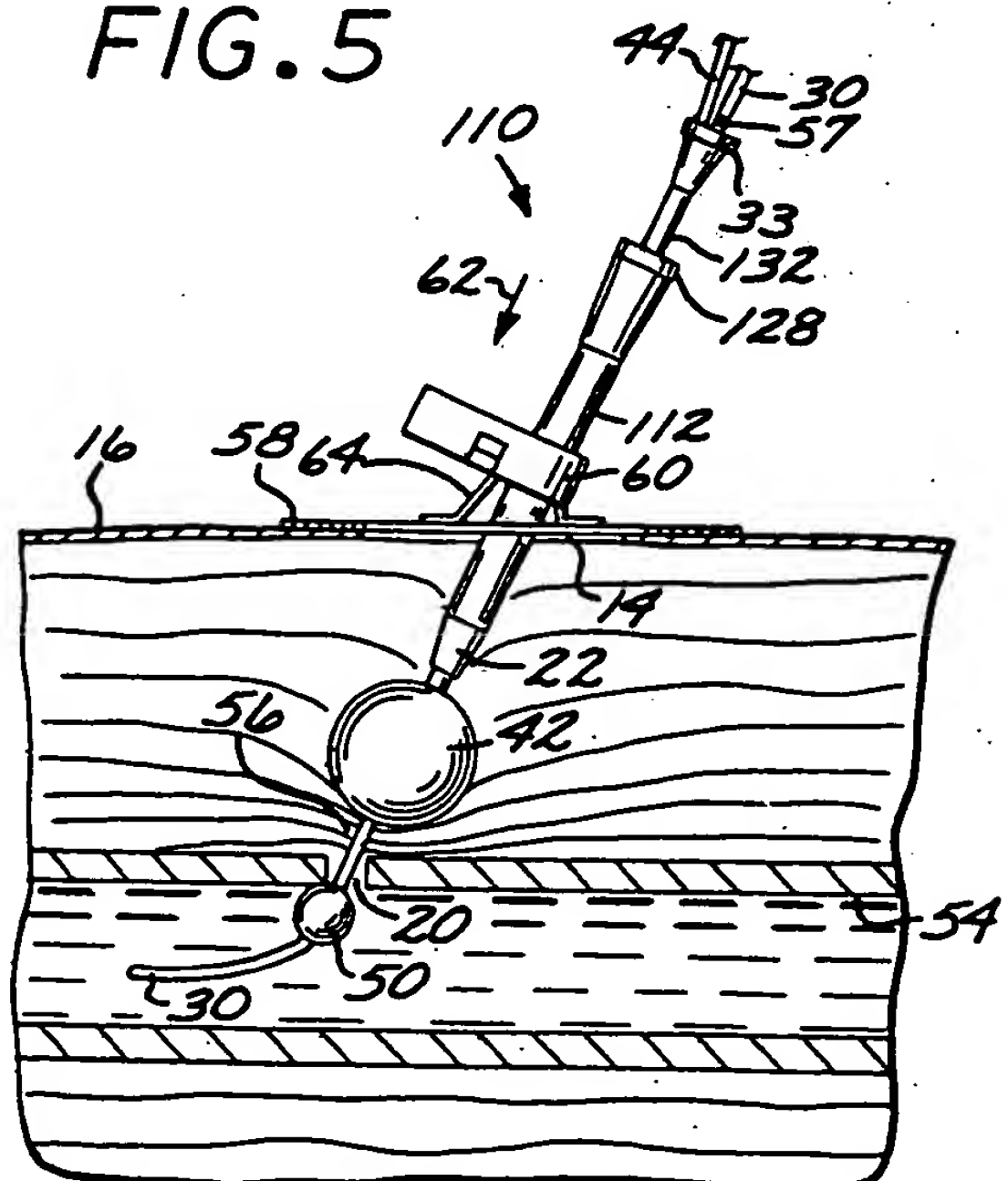


FIG. 5



# INTERNATIONAL SEARCH REPORT

national application No.

PCT/US 96/ 14486

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 46-53  
because they relate to subject matter not required to be searched by this Authority, namely:  
PCT Rule 39.1(iv) Method for treatm of human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. Application No

PCT/US 96/14486

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9402072	03-02-94	US-A- 5413571	09-05-95
		AU-A- 4675093	14-02-94
		CA-A- 2140349	03-02-94
		EP-A- 0684788	06-12-95
		JP-T- 8501707	27-02-96
		US-A- 5540715	30-07-96
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US-A-5419765	30-05-95	US-A- 5330446	19-07-94
		US-A- 5129882	14-07-92
		CA-A- 2126633	17-08-95
		EP-A- 0668086	23-08-95
		JP-A- 7227423	29-08-95
		DE-D- 69115009	11-01-96
		EP-A- 0493810	08-07-92
		JP-A- 5123329	21-05-93
		US-A- 5221259	22-06-93
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EP-A-0637431	08-02-95	US-A- 5462561	31-10-95
		CA-A- 2126303	06-02-95
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EP-A-0557963	01-09-93	CA-A- 2089999	25-08-93
		US-A- 5405360	11-04-95
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MAY - 7 1997

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# INTERNATIONAL SEARCH REPORT

Intern. Application No  
PCT/US 96/14486

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,94 02072 (SHERWOOD MEDICAL CO ;KATSAROS GEORGES (BE); THOMAS DAVID GRAEME (U) 3 February 1994  see page 6, line 24 - page 7, line 6 see page 11, line 13 - line 16 see page 14, line 23 - line 28 see page 16, line 16 - line 25 see page 22, line 25 - page 23, line 1 see figures 2,7-12	1,2,5,7, 13,14, 20,21, 32,41
X	--- -/--	19,23

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

**\* Special categories of cited documents :**

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*&\* document member of the same patent family

Date of the actual completion of the international search

7 January 1997

Date of mailing of the international search report

15. 01. 97

Name and mailing address of the ISA

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Fax (+31-70) 340-3016

Authorized officer

Chabus, H

# INTERNATIONAL SEARCH REPORT

Intern    nal Application No  
PCT/US 96/14486

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US,A,5 419 765 (WELDON THOMAS D ET AL) 30 May 1995</p> <p>see column 2, line 10 - line 26 see column 6, line 23 - line 33 see column 7, line 7 - line 15 see column 13, line 5 - line 16 see figures 4-13,22A-24D</p> <p style="text-align: center;">---</p>	<p>1,2, 4-16, 19-25, 29-31, 33,34, 37-40, 42,43</p>
A	<p>EP,A,0 637 431 (VODA JAN) 8 February 1995</p> <p>see column 5, line 43 - column 6, line 1 see figures 3-5</p> <p style="text-align: center;">---</p>	<p>17,18, 26,27, 35,36, 44,45</p>
A	<p>EP,A,0 557 963 (UNITED STATES SURGICAL CORP) 1 September 1993</p> <p>see column 4, line 30 - line 49 see column 7, line 26 - line 31 see column 8, line 7 - line 17 see figures 1-5</p> <p style="text-align: center;">-----</p>	<p>3,28</p>